

# EXHIBIT 33

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: )  
 ) CA No. 01-12257-PBS  
PHARMACEUTICAL INDUSTRY AVERAGE )  
WHOLESALE PRICE LITIGATION ) Pages 1 - 98  
 )

TUTORIAL AND MOTION HEARING  
BEFORE THE HONORABLE PATTI B. SARIS  
UNITED STATES DISTRICT JUDGE

United States District Court  
1 Courthouse Way, Courtroom 19  
Boston, Massachusetts  
July 8, 2009, 2:05 p.m.

LEE A. MARZILLI  
OFFICIAL COURT REPORTER  
United States District Court  
1 Courthouse Way, Room 3205  
Boston, MA 02210  
(617)345-6787

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## 1 A P P E A R A N C E S:

## 2 FOR THE PLAINTIFFS:

3 JOANNE M. CICALA, ESQ., JAMES P. CARROLL, ESQ.,  
 4 JOCELYN NORMAN, ESQ., and KATHRYN B. ALLEN, ESQ.,  
 Kirby McInerney, LLP, 101 College Street, Dripping Springs,  
 Texas, 78620, for the City of New York and New York  
 5 Counties.

6 MICHAEL WINGET-HERNANDEZ, ESQ., 3112 Windsor Road,  
 Austin, Texas, 78703, of Counsel, Kirby McInerney.

7  
8 FOR THE DEFENDANTS:

9 JOHN T. MONTGOMERY, ESQ. and JOHN P. BUEKER, ESQ.  
 Ropes & Gray, LLP, One International Place, 02110,  
 10 for Schering and Warrick.

11 CHRISTOPHER C. PALERMO, ESQ., Kelley Drye & Warren,  
 LLP, 101 Park Avenue, New York, New York, 10178,  
 12 for Dey, Inc.

## 13 ALSO PRESENT:

14 JEFFREY FAUCI, ESQ., Assistant United States Attorney,  
 Office of the United States Attorney, 1 Courthouse Way,  
 15 Boston, Massachusetts, 02210.

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## 1 P R O C E E D I N G S

2 THE CLERK: In Re: Pharmaceutical Industry  
 3 Average Wholesale Price Litigation, Civil Action 01-12257,  
 4 will now be heard before this Court. Will counsel please  
 5 identify themselves for the record.

6 MS. CICALA: Joanne Cicala from Kirby McInerney on  
 7 behalf of the City of New York and New York counties.

8 MR. CARROLL: James Carroll from Kirby McInerney  
 9 on behalf of the City of New York and New York counties.

10 MR. BERMAN: Michael Winget-Hernandez. I'm of  
 11 counsel with Kirby.

12 MR. MONTGOMERY: John Montgomery, Ropes & Gray,  
 13 for Schering and Warrick.

14 MR. BUEKER: Good afternoon, your Honor. John  
 15 Bueker, also from Ropes & Gray, for Schering and Warrick.

16 MS. NORMAND: Jocelyn Normand from Kirby  
 17 McInerney.

18 THE COURT: For the plaintiffs?

19 MS. NORMAND: Plaintiffs.

20 MS. ALLEN: Kathryn Allen from Kirby McInerney,  
 21 representing the City of New York and the New York counties.

22 THE COURT: We had scheduled today a tutorial.

23 Oh, somebody else popping up.

24 MR. PALERMO: Good afternoon, your Honor. Chris  
 25 Palermo, Kelley, Drye & Warren, on behalf of Dey and the

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## 1 I N D E X

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3 WITNESS

## DIRECT CROSS REDIRECT RECROSS

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5 SUMANTH ADDANKI

6 By Mr. Bueker: 9

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1 Mylan defendants.

2 THE COURT: Did you want to come up here?

3 MR. PALERMO: I'm fine right here, your Honor.

4 THE COURT: Maybe out the door? Is there anyone  
 5 else who wants to introduce themselves? All right.

6 So we had scheduled a tutorial today. Were you  
 7 planning on introducing witnesses?

8 MR. MONTGOMERY: Yes, your Honor.

9 THE COURT: All right. Were you as well? Is this  
 10 a joint?

11 MS. CICALA: We may or may not introduce a witness  
 12 in connection with the tutorial, depending on defense's  
 13 presentation. We had conferred yesterday and agreed to an  
 14 order, of course, pending the Court's agreement as well.

15 THE COURT: What are you planning on?

16 MR. MONTGOMERY: Our proposal was to present first  
 17 Dr. Addanki, who is here today. Then I take it from  
 18 Ms. Cicala's comment that depending on Dr. Addanki's  
 19 testimony, that Mr. Devor may then testify.

20 MS. CICALA: Yes.

21 MR. MONTGOMERY: And that would conclude the  
 22 tutorial exercise. We then discussed, subject, your Honor,  
 23 to your preferences, that we would then follow the tutorial  
 24 with the scheduled argument on summary judgment; and I think  
 25 we've agreed on an order there, that Ms. Cicala would go

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1 first, we would go second. There is one item as to which we  
2 did not reach agreement. If the proposal that we have  
3 agreed upon is acceptable to your Honor, we ought to address  
4 that one item.

5 THE COURT: That seems fine. My biggest concern  
6 is, as a practical matter, it's ten past 2:00, and we'll  
7 stop around 5:00, and usually I give my court reporter a  
8 break in there somewhere, which no matter how hard I try  
9 ends up being fifteen, twenty minutes. So just --

10 MR. MONTGOMERY: We understand.

11 THE COURT: -- that's the reality of it.

12 MS. CICALA: That's fine, your Honor. What  
13 Mr. Montgomery is alluding to, your Honor may be aware that  
14 defendants had filed a Daubert motion in connection with  
15 Mr. Devor's proffered expert testimony, and we are of the  
16 view that the Daubert motion should be heard first in  
17 connection with today's hearing, given that in terms of  
18 Dr. Addanki's testimony, for example, Dr. Addanki is  
19 testifying on two subjects primarily.

20 THE COURT: So you filed a Daubert?

21 MS. CICALA: No.

22 THE COURT: They filed it?

23 MS. CICALA: They did.

24 THE COURT: So let's just not do that now.

25 MS. CICALA: Well, if I may be heard on this just

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1 for one moment, your Honor.

2 THE COURT: Yes.

3 MS. CICALA: What is at issue in the Daubert is  
4 identical to the testimony of Dr. Addanki in terms of the  
5 reliability of Mr. Devor's report. So there is a complete  
6 identity of issues between the Daubert challenge and what  
7 you're going to hear from Dr. Addanki in so as far as he  
8 addresses the reliability of Mr. Devor's conclusions, and  
9 those same arguments --

10 THE COURT: This is only a tutorial. I'm not  
11 going to accept a Daubert challenge to anyone anyway. I  
12 mean, the theory of it is, it's -- I'm sorry I missed, I  
13 didn't notice that there was a Daubert motion even pending  
14 or something to be addressed today. So you want to ask him  
15 questions that relate to the Daubert, is that it?

16 MS. CICALA: No. We're here for two purposes,  
17 right, your Honor? We're here for the tutorial and also for  
18 the oral argument. And the Daubert motion touches on -- the  
19 tutorial -- when it comes to Mr. Devor's report, defendants  
20 make the same argument, whether it's in the tutorial or in  
21 connection with the summary judgment motions or the Daubert.

22 THE COURT: I haven't read, I confess, I've read  
23 the motions for summary judgment, but I have not read the  
24 Daubert motion. It's catching me a little bit by surprise,  
25 so I don't even know how to rule on it. I don't understand

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1 the practical implications. Do you want to ask him  
2 questions that are relating to the Daubert?

3 MS. CICALA: No. The practical implications is  
4 that your Honor is going to hear argument regarding the  
5 reliability today of Mr. Devor's conclusions. The Daubert  
6 motion makes the exact same argument.

7 THE COURT: But it won't add to the length of the  
8 tutorial, does it?

9 MS. CICALA: Well, I guess it would depend how the  
10 Daubert is ruled upon.

11 THE COURT: You know what, I don't understand it  
12 well enough. Let's just get going, and at some point pop up  
13 and say, "See, this is what I mean," okay?

14 MS. CICALA: That's fine.

15 THE COURT: Because my biggest concern is getting  
16 through at least the two live witnesses today, and I'm not  
17 sure that -- as far as I'm concerned, this is not a mini  
18 "trial," you know, on knowledge or something like that. It  
19 really should be pretty bare bones as to how FUL is set,  
20 right?

21 MS. CICALA: Well, actually, your Honor, yes,  
22 there's no disagreement between the parties that CMS  
23 exercised discretion when setting the FUL. There's no  
24 disagreement on that subject, so this could be very quick.

25 The other prong, though, is the reliability of

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1 Mr. Devor's conclusions, and that's why I raise the Daubert  
2 because that's the subject of the Daubert challenge as well.  
3 So there's an efficiency perhaps to addressing this once now  
4 while we're all here.

5 THE COURT: I don't know. Let's just get him on  
6 and off. Let's just do this, and then I'll worry about that  
7 later because it's not even clear to me we're going to  
8 finish him.

9 MS. CICALA: Thank you, your Honor.

10 MR. BUEKER: Then, your Honor, the defendants  
11 would call Dr. Addanki to the stand.

12 THE COURT: Thank you.

13 SUMANTH ADDANKI  
14 having been first duly sworn, was examined and testified as  
15 follows:

16 THE CLERK: Would you please state your name and  
17 spell it for the record.

18 THE WITNESS: My name is Sumanth Addanki. That's  
19 spelled S-u-m-a-n-t-h A-d-d-a-n-k-i.

20 DIRECT EXAMINATION BY MR. BUEKER:

21 Q. Dr. Addanki, would you introduce yourself or  
22 reintroduce yourself, I guess, to the Court.

23 A. Yes. I'm Sumanth Addanki. I'm an economist. I'm  
24 working on behalf of the group of defendants in this case.

25 Q. And is it accurate to say, Dr. Addanki, that you've

<p style="text-align: right;">Page 10</p> <p>1 testified previously before this Court as an expert on  2 pharmaceutical pricing matters?  3 A. I have, your Honor.  4 Q. And would you briefly remind the Court of some of your  5 qualifications in the area of pharmaceutical pricing.  6 A. Your Honor, I have a Ph.D. in economics, and I have  7 spent the last almost 30 years in economic research of  8 various kinds. And over the last two decades, I've done a  9 great deal of research on the pharmaceutical industry,  10 including most recently a variety of research assignments on  11 pricing in the pharmaceutical industry. And I appeared  12 before your Honor in connection with the MDL about two and a  13 half years ago in December of 2006.  14 THE COURT: Well, have you done any of this work  15 on pricing in a nonlitigation context?  16 THE WITNESS: I've done some work on pricing in a  17 nonlitigation context, and certainly a lot of it in research  18 having nothing to do with AWP litigation.  19 THE COURT: Is it other litigation?  20 THE WITNESS: Sometimes litigation and sometimes  21 other contested proceedings of arbitrations or other  22 proceedings of that kind.  23 Q. And, Dr. Addanki, have you prepared a PowerPoint  24 presentation to help you assist in presenting your tutorial  25 today?</p>	<p style="text-align: right;">Page 12</p> <p>1 were reasonably representative of the larger group of drugs  2 for which CMS sets FULs. And those nine drugs had 31 FULs  3 associated with them, and those are in fact the FULs that I  4 studied, your Honor.  5 Q. So the Court has some idea of where we're headed, would  6 you summarize briefly for the Court at this point the  7 conclusions that you reached as an economist based on your  8 examination of the data that showed how CMS set FULs.  9 A. Yes, of course. Although CMS's regulation specifies  10 that the FUL shall be set as 150 percent of the lowest  11 published price available, what I find from my analysis,  12 your Honor, is that in the overwhelming majority of cases,  13 CMS did not follow that rule. Rather, what they did was,  14 using a variety of market-risk intelligence, CMS exercised  15 its discretion on a case-by-case basis and chose FULs and  16 maintained FULs that were higher than the simple rule would  17 have predicted.  18 And, finally --  19 THE COURT: Excuse me. What time period are we  20 talking about?  21 THE WITNESS: We're talking about the period  22 from -- I think FULs ranged from -- set from 1996 to about  23 2005, your Honor.  24 THE COURT: So you looked at all the --  25 THE WITNESS: The entire, exactly, all FULs that</p>
<p style="text-align: right;">Page 11</p> <p>1 A. I have.  2 MR. BUEKER: Your Honor, I shared a copy of this  3 with counsel for plaintiffs this morning, and they have a  4 copy. I have several copies for the Court and the clerk.  5 THE COURT: I look forward to them. I don't know  6 what a hearing would be without them.  7 MR. BUEKER: And I think it's also up on the  8 screen. And Dr. Addanki has the mouse to be able to control  9 it as he sees fit, but I thought the PowerPoint and hard  10 copy helped.  11 Q. Would you, Dr. Addanki, just kind of briefly describe  12 what you've been asked to do in connection with this case.  13 A. Primarily my assignment had two parts, your Honor. The  14 first part was to analyze how CMS actually sets FULs; and  15 the second part was, in light of the results of my analysis  16 of how CMS sets FULs, to evaluate the plaintiffs' claims  17 that had the defendants reported alternative prices to the  18 compendia, that the FULs set by CMS would have been  19 different as a result, would have been lower as a result.  20 Q. And so it's clear for the Court, did you look at the  21 nine drugs that were at issue in this proceeding and examine  22 how CMS set the FULs for those nine drugs?  23 A. Yes, I did. I understand that nine drugs were selected  24 for this first phase of study, and that those nine drugs,  25 the parties have agreed and CMS witnesses have testified,</p>	<p style="text-align: right;">Page 13</p> <p>1 were set during the period that I understood to have been  2 identified as the relevant period.  3 MR. BUEKER: And to jump in here, your Honor, I  4 think in CMO 33, what you did was set a relevant period,  5 which was 1997 to 2005, and actually direct the parties to  6 choose five drugs apiece to look at as a targeted bit of  7 discovery, and that's been the focus of this presentation.  8 A. And my final conclusion was, in light of what I found  9 about how CMS had set the FULs that I've just explained to  10 you, that I've just described to you, the contention, the  11 idea, the proposition that had the defendants reported  12 transactions prices rather than undiscounted list prices,  13 that the FULs set by CMS would have been lower, that makes  14 no economic sense in light of what I found about how CMS  15 sets the FULs.  16 Q. Before we return to kind of what you found, would you  17 just describe for the Court your methodology. What did you  18 do to arrive at your conclusions?  19 A. Certainly. I start, your Honor, with the regulation  20 itself that sets forth how the FULs shall be set. And I've  21 got it up on the slide here. It says that "CMS is required  22 to establish a FUL if there are at least three suppliers of  23 A-rated or therapeutically equivalent products." And it  24 further says that "The FUL is to be set at 150 percent of  25 the lowest published price for the 100-count package size or</p>

<p style="text-align: right;">Page 14</p> <p>1 the most commonly-available package size."  2 So it really sets forth a pretty straightforward  3 rule: If there are three or more alternatives available,  4 set the FUL at 150 percent of the lowest published price  5 available.  6 I further understand that the sources that CMS  7 refers to for the published prices are the three pricing  8 compendia, Medi-Span, Blue Book, which is FDB's publication,  9 and Red Book.  10 Q. Would you walk the Court through, Dr. Addanki, the  11 steps you took to determine whether CMS in practice actually  12 followed this rule.  13 A. Yes. One of the things we're helped by in this whole  14 exercise is that when CMS sets a FUL, your Honor, it issues  15 a letter of transmittal to state Medicaid agencies informing  16 the Medicaid agencies that a FUL has been changed or set.  17 And what that transmittal includes is information about the  18 drug at issue, the drug for which the FUL is being set, the  19 period during which that FUL will be effective. And it also  20 sets forth in the transmittal the month during which the  21 prices that CMS consulted in setting its FULs, the prices  22 that CMS relied upon in setting its FUL, were current. So  23 I'll refer to that as the current month from now on.  24 Now, I want to note that CMS does not specify  25 which price it used as the basis for the FUL that it's</p>	<p style="text-align: right;">Page 16</p> <p>1 THE WITNESS: That's right.  2 THE COURT: Because AMPs are not published?  3 THE WITNESS: That's right, exactly.  4 THE COURT: Are they published internally to the  5 agency?  6 THE WITNESS: Within CMS?  7 THE COURT: Yes. Are they published in any kind  8 of format like a Blue Book or something internal to the  9 agency?  10 THE WITNESS: If they are, I'm not aware of it,  11 your Honor. I don't know.  12 THE COURT: So at least based on your review of  13 the documents, when CMS refers to published prices, they're  14 not picking up AMP in any way?  15 THE WITNESS: I understand that when CMS refers to  16 published prices, they're speaking about these three types  17 of prices in the three compendia that I mentioned.  18 Q. So you were walking the Court through the steps you  19 took to find the universe of published prices CMS had before  20 it.  21 A. Yes. The first step is to identify all of the NDCs  22 whose prices might be relevant to this exercise because  23 there were therapeutic equivalents that were available at  24 the time, your Honor. And in doing that, I followed a  25 couple of steps, and I'll run us through them very quickly,</p>
<p style="text-align: right;">Page 15</p> <p>1 issuing. It does, however, say in the transmittal what  2 compendium the price came from. So it would specify whether  3 it was Blue Book, which was the First DataBank price, or  4 Red Book or Medi-Span. It doesn't say which price it used  5 from there. It does tell you which month those prices were  6 current in.  7 Q. So just so we're clear, how is it that looking at the  8 transmittal you determine what the universe of prices CMS  9 had before it when it set the FUL is?  10 A. Well, the transmittal only gives you the first step in  11 that process. Again, going back to what the regulation  12 says, we need to identify all of the therapeutically  13 equivalent products available at the time during that  14 current month and identify the prices for such products that  15 were valid during that current month. And that's the  16 process that I can quickly walk us through, your Honor.  17 THE COURT: So when you say published prices, what  18 are we talking about, AWP?  19 THE WITNESS: Yes, your Honor.  20 THE COURT: WAC, and what else?  21 THE WITNESS: And direct price.  22 THE COURT: And the direct price.  23 THE WITNESS: The direct price, those are the  24 three prices.  25 THE COURT: But not AMPs?</p>	<p style="text-align: right;">Page 17</p> <p>1 and I'm happy to explain any of them in more length if you'd  2 like, your Honor.  3 The first step was that in FDB, in First DataBank  4 data, there actually is a field called the GCN sequence  5 number which identifies whether a particular NDC belongs to  6 a particular generic grouping or not. So that's my starting  7 point. I identify all the NDCs that correspond to the  8 GCN -- I'm sorry for the alphabet soup, your Honor, but  9 that's the nature of this industry -- that correspond to the  10 GCN to which the FUL applies. But because FDB does not have  11 necessarily all of the NDCs that might be relevant in its  12 own database, I then look at how those NDCs that FDB  13 identified as being in the GCN were described in the  14 Red Book and Medi-Span data, capture the descriptions of  15 these NDCs that appear in the Medi-Span and Red Book data,  16 and then search those compendia for other NDCs that have the  17 same description. And I've got up here, your Honor --  18 THE COURT: You told me, but GCN is again?  19 THE WITNESS: It's Generic Code Number.  20 THE COURT: As opposed to NDC?  21 THE WITNESS: As opposed to NDC, yes.  22 THE COURT: Is it for branded?  23 THE WITNESS: No. NDC is just the National Drug  24 Code. It's just a code that identifies --  25 THE COURT: So what's generic code number?</p>



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1 THE WITNESS: The generic code number is the  
 2 grouping of the generic formulations that can be considered  
 3 to be substituted for one another and that pharmacies can  
 4 substitute for one another when a prescription is presented.  
 5 Q. So maybe I can clear this up with a question. Would  
 6 all, Dr. Addanki, Clonazepam, for example, NDCs have the  
 7 same GCN?  
 8 A. To the extent that they appear in FDB, your Honor, the  
 9 GCN code would say it's the Clonazepam GCN. Of course,  
 10 those that don't appear in the First DataBank compendium but  
 11 only appear in Red Book or Medispan won't have it because  
 12 those compendia don't have a GCN field. But we are able to  
 13 identify the NDCs that would need to be added from those  
 14 compendia by means of the descriptions, and the slide I've  
 15 got up here, your Honor, shows the descriptions that applied  
 16 to the Clonazepam .5 milligram GCN.  
 17 Q. Dr. Addanki, once you had a comprehensive list of all  
 18 of the NDCs that needed to be considered, what did you do  
 19 next?  
 20 A. Well, again, if you recall, the regulation says that we  
 21 have to restrict this to prices for A-rated therapeutic  
 22 equivalents. So the next step was to make sure that I did  
 23 not have in there any NDCs that were not A-rated therapeutic  
 24 equivalents, and the basic source for that is the Orange  
 25 Book, the FDA's Orange Book. And by direct reference to the

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1 Orange Book and using data that the compendia gathered from  
 2 the Orange Book, I was able to discard from the set any NDCs  
 3 that were not A-rated therapeutic equivalents.  
 4 Q. What did you do next?  
 5 A. The next step was, of course, to then go and gather the  
 6 prices, your Honor, for these NDCs, these A-rated  
 7 therapeutic equivalents; and the three sources that I used  
 8 were the FDB, First DataBank data, the Red Book, and  
 9 Medi-Span.  
 10 Now, I can't actually show you examples of the  
 11 data because the data I used were electronic, but some of  
 12 these electronic data also do appear in hard-copy form, and  
 13 I've at least got a couple of those hard-copy examples here  
 14 on the slide. But the data that we used were electronic  
 15 data that the compendia publishers provide.  
 16 Q. Dr. Addanki, are those the same sources of information  
 17 as are set forth in the CMS transmittal?  
 18 A. Yes.  
 19 Q. And the prices that you collected, what prices did you  
 20 collect?  
 21 A. We collected the direct price, the WAC, and the AWP.  
 22 THE COURT: And how often are they adjusted?  
 23 THE WITNESS: It depends, your Honor. The  
 24 compendia record all of the price postings that were made  
 25 for a particular NDC. Because the different compendia

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1 handle the data in slightly different ways, they each have  
 2 their own ways of identifying when a posting is valid and  
 3 when it's been superseded.  
 4 THE COURT: You say FUL was set on a certain set  
 5 of numbers. Is it that way forever, or does the agency  
 6 adjust them quarterly, yearly?  
 7 THE WITNESS: Oh, the agency can adjust FULs --  
 8 THE COURT: I know they can, but what I'm  
 9 saying --  
 10 THE WITNESS: -- and do --  
 11 THE COURT: And do.  
 12 THE WITNESS: -- and do, from the data that I have  
 13 seen, at extremely variable intervals. It can be a matter  
 14 of weeks and months, it can be a matter of years before they  
 15 decide to change a FUL.  
 16 THE COURT: And we don't know what alerts them to  
 17 make a change?  
 18 THE WITNESS: Well, the data that are available to  
 19 them are current data, the electronic data, the current  
 20 data. So at least the one thing, as far as I know, that is  
 21 not preventing them from making any change is, or not  
 22 impeding them from making any change, is availability of  
 23 up-to-date data. But beyond that, I don't know what it is  
 24 that prompts them to make a change for some FULs --  
 25 THE COURT: But there's no regulation or policy or

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1 practice that you could discern? It was catch-as-catch-can?  
 2 THE WITNESS: It appears to be. It appears to be,  
 3 and I'll get into that in a little more detail as I describe  
 4 the results.  
 5 Q. And, Dr. Addanki, once you had this list of prices  
 6 compiled for all the relevant NDCs, what did you do?  
 7 A. Well, the last stage was, in identifying the prices  
 8 that would have been available from which to set the FUL,  
 9 was to eliminate any prices that were obsolete or invalid  
 10 because they were superseded, or invalid because the NDC  
 11 itself had been declared obsolete. So it was really a  
 12 question of winnowing out prices that could not have been or  
 13 shouldn't have been used as a basis for a FUL; and that  
 14 gives us, finally, an array of prices, your Honor, and I'll  
 15 show you an example of it.  
 16 But the other thing I did do was, wherever I had a  
 17 FUL that CMS documents, testimony, or the CMS witnesses had  
 18 made reference to, to the extent possible, I confirmed the  
 19 results of my analysis with whatever information I could  
 20 find from CMS.  
 21 Q. Now, Dr. Addanki, you mentioned you had an example of  
 22 the resulting array.  
 23 A. Yes.  
 24 THE WITNESS: Your Honor, if I may step down, and  
 25 I've got a poster board with it on it?

<p style="text-align: right;">Page 22</p> <p>1 THE COURT: Yes.</p> <p>2 THE WITNESS: I'm not sure if you can see it from</p> <p>3 over there, your Honor.</p> <p>4 THE COURT: I have it here.</p> <p>5 MR. BUEKER: It's on Slide 17, your Honor.</p> <p>6 THE WITNESS: It's the Clonazepam .5 milligrams.</p> <p>7 It's the one, actually, I've been talking about as the</p> <p>8 example throughout so far. And this is the FUL that was set</p> <p>9 in November, 2001, to be in effect from January, 2002, and</p> <p>10 it was based on prices that were current as of April, 2001.</p> <p>11 And all that information is from the transmittal letter.</p> <p>12 The FUL was set, your Honor, at .2455, which is</p> <p>13 24.55 cents per pill. And I've got the prices arrayed here</p> <p>14 that were the results of my analysis of identifying all of</p> <p>15 the prices that CMS could have used, based on the</p> <p>16 regulation, and arrayed in order, in diminishing order of</p> <p>17 price. And as we can see, the FULs that they picked matches</p> <p>18 this band in orange: Actavis which had a WAC of .1637,</p> <p>19 resulting in a FUL, if you adjust for the rounding problem,</p> <p>20 of .2455. And I did verify this with a CMS document, and</p> <p>21 indeed Actavis was called Purepak at that time, and the FUL</p> <p>22 was in fact based on exactly that NDC.</p> <p>23 What I'd like to point out, though, is that CMS</p> <p>24 did not elect to set the FUL at 150 percent of the lowest</p> <p>25 published price here. The lowest published price was</p>	<p style="text-align: right;">Page 24</p> <p>1 this and said exactly as Dr. Addanki has said; that when CMS</p> <p>2 was exercising its discretion to pass over lower published</p> <p>3 prices, what it was doing was balancing two competing</p> <p>4 concerns, the first being cost savings, obviously pushing it</p> <p>5 lower, but at the same time access. And so when asked</p> <p>6 repeatedly about why CMS passed over lower published prices,</p> <p>7 the answer was "access."</p> <p>8 THE COURT: It went to the highest price, not to</p> <p>9 the lowest. I mean --</p> <p>10 THE WITNESS: No. Your Honor, there are a lot of</p> <p>11 prices higher than that that they could have gone to.</p> <p>12 There's a full array of prices, your Honor. It's just that</p> <p>13 the colors start only with the one that they picked. So,</p> <p>14 for instance, they could have used the UDL WAC of 17 cents.</p> <p>15 THE COURT: Oh, I see. Oh, I'm sorry. Then I</p> <p>16 misunderstood. So the yellow is only --</p> <p>17 THE WITNESS: It's only highlighting the ones</p> <p>18 below.</p> <p>19 THE COURT: I see, I see. So all of it --</p> <p>20 THE WITNESS: All the prices are valid prices that</p> <p>21 were available to CMS.</p> <p>22 THE COURT: On both side of this?</p> <p>23 THE WITNESS: Exactly.</p> <p>24 THE COURT: I see, I see.</p> <p>25 THE WITNESS: So they chose the orange one, but</p>
<p style="text-align: right;">Page 23</p> <p>1 Major's WAC of .0799, which would have resulted in a FUL of</p> <p>2 slightly under 12 cents, your Honor. They passed over that</p> <p>3 as well as another Teva NDC, a direct price of .0989, which</p> <p>4 would have resulted in a FUL of slightly under 15 cents.</p> <p>5 They elected to set a FUL that was quite a bit higher,</p> <p>6 about --</p> <p>7 THE COURT: Was anyone asked why point-blank about</p> <p>8 this spread here, this cluster?</p> <p>9 THE WITNESS: It was a question of access, your</p> <p>10 Honor, availability.</p> <p>11 THE COURT: No, no, did someone ask someone at CMS</p> <p>12 who's responsible about this cohort, why they picked the</p> <p>13 highest number rather than the lowest number?</p> <p>14 MR. BUEKER: I can answer that question most</p> <p>15 directly, I think, your Honor. The answer is twofold:</p> <p>16 First, the individual who actually was responsible for</p> <p>17 setting this was a woman by the name of Cindy Bergen, who we</p> <p>18 were denied under Touhy the opportunity to depose, number</p> <p>19 one. However, Sue Gaston, who we were allowed to depose,</p> <p>20 was asked about this particular FUL --</p> <p>21 THE COURT: Who is she?</p> <p>22 THE WITNESS: Sue Gaston is another individual at</p> <p>23 CMS who set FULs during the relevant period of time,</p> <p>24 actually worked side by side with Ms. Bergen and looked</p> <p>25 at -- it's Exhibit 5 to Ms. Gaston's deposition -- looked at</p>	<p style="text-align: right;">Page 25</p> <p>1 they passed over the seven ones that are highlighted in</p> <p>2 yellow.</p> <p>3 And the one last thing I'd like to point out on</p> <p>4 this chart is, the data are not shown on this chart, your</p> <p>5 Honor, but the Teva NDC that I just mentioned which has the</p> <p>6 direct price of .0989 was a very large NDC in terms of</p> <p>7 sales. It accounted for well over 40 percent of the</p> <p>8 reimbursement under Medicaid throughout this relevant period</p> <p>9 for this drug, for Clonazepam .05 milligram.</p> <p>10 Q. Dr. Addanki, do you have another example of the results</p> <p>11 of your analysis showing another one of these arrays?</p> <p>12 THE COURT: Can I ask you, though, did you see any</p> <p>13 situations where suppose every -- what were the AMPs for</p> <p>14 these drugs?</p> <p>15 THE WITNESS: The Teva AMP for this direct price,</p> <p>16 your Honor, is slightly under 3 cents.</p> <p>17 THE COURT: And was that roughly where everybody</p> <p>18 else was?</p> <p>19 THE WITNESS: I don't know what everyone's AMPs</p> <p>20 were.</p> <p>21 THE COURT: Three cents, 5 cents, 4 cents?</p> <p>22 THE WITNESS: I don't know, your Honor.</p> <p>23 THE COURT: Suppose they were all sort of in that</p> <p>24 range, you know, 4 cents, 3 cents, 6 cents, and all lowest</p> <p>25 were there, did you see any examples like that where they</p>



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1 would then just go to a higher price? In other words, if  
 2 everybody told the truth that it's AMP, would it have  
 3 shifted the dynamic downward?

4 THE WITNESS: If everyone told them what their  
 5 AMPs were?

6 THE COURT: Their theory is that a WAC is an AMP.

7 THE WITNESS: Okay.

8 THE COURT: If everyone in this group had actually  
 9 reported the AMPs in your yellow and orange highlighting,  
 10 would that have shifted the price down?

11 THE WITNESS: Based on what I see CMS doing, your  
 12 Honor -- and I'm going to talk about this in more detail --  
 13 based on what I see CMS doing in setting the FULs, no.

14 THE COURT: Did anyone ask that? In other words,  
 15 I understand what you're saying here is that within the  
 16 range between 16 cents and 7 cents, they picked the  
 17 16 cents seemingly randomly, that they picked a number that  
 18 wasn't the rock bottom but was near the bottom. But suppose  
 19 the nearer the bottom was a lot lower, it was in the  
 20 vicinity of 3 or 4 cents, let's say, for all of these, would  
 21 that have shifted the paradigm down?

22 THE WITNESS: That's a very interesting question  
 23 you ask. If I can reask the question, let me see if I've  
 24 got your question right.

25 THE COURT: I'm sure you can think about it in a

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1 more sophisticated way, but suppose they have the AMPs  
 2 instead of the WACs, so that these numbers are all in the  
 3 range of 3, 4, 5 cents, and they're all at the bottom there,  
 4 wouldn't that have at least shifted it down a few pennies?

5 THE WITNESS: There are instances where -- okay,  
 6 in this instance, your Honor, the difference between the FUL  
 7 that they set and the FUL that they could have set based on  
 8 just blind application of the reg, and they certainly were  
 9 entitled to have set based on its being a published price,  
 10 is only a factor of two. It's 12 cents to 25 cents. There  
 11 are cases where it's --

12 THE COURT: That's actually huge. I mean --

13 THE WITNESS: But there are cases where it's much  
 14 bigger. There are cases where it's much bigger than that,  
 15 where you could have had a two order of magnitude difference  
 16 between the FUL that was available to them under the reg and  
 17 based on the published prices that were out there and the  
 18 one that they actually picked was way up there. There is no  
 19 particular pattern to either the percentage or the dollar or  
 20 cent difference between where they could have gone and where  
 21 they actually went.

22 THE COURT: Essentially -- I'm trying to  
 23 understand -- you're thinking is pretty much random --

24 THE WITNESS: No.

25 THE COURT: -- in the sense that you can't predict

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1 what they do in any given situation.

2 THE WITNESS: You cannot predict it if you believe  
 3 that all they look at is published prices, that's correct.

4 THE COURT: Well, we know they're flat out  
 5 violating this regulation. So assume you're right that they  
 6 do that systematically. I don't know what I do with that  
 7 legally, but assume you're right, they flat out violate the  
 8 regulation systematically. And it may be for benign  
 9 purposes, but they violate it. So what you're saying here  
 10 is, you can't really predict if everybody had truthfully  
 11 reported their WACs so that that was the lowest published  
 12 price, so instead of the published price being 16 cents, it  
 13 was 5 cents, and the next one down is 4 cents, and the next  
 14 one -- you couldn't predict what they would do with that.  
 15 Is that what you're trying to --

16 THE WITNESS: What I'm saying is that without  
 17 knowing what other intelligence they were using to make the  
 18 determination, your Honor, that in this case, I'm not going  
 19 to go to 12 cents, I'm not going to go to 15 cents, I'm not  
 20 going to go to 18 cents; I'm going to go to 25 cents.  
 21 Whatever intelligence was there -- and the testimony is that  
 22 they gathered a lot of intelligence -- whatever intelligence  
 23 was telling them that "In order to satisfy my access and  
 24 cost requirements objectives, here's what I'm going to set  
 25 the FUL," that intelligence is still out there; and whether

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1 people are reporting AMPs or people are reporting ASPs or  
 2 people are reporting whatever they're reporting, that  
 3 intelligence doesn't go away.

4 THE COURT: Well, did any of these folks say in  
 5 the depositions that they actually looked at the AMP?

6 THE WITNESS: I don't recall whether anyone said  
 7 they looked at the AMP or not.

8 THE COURT: So as far as when you did your review,  
 9 you personally were only looking at what happened with  
 10 respect to the published prices in the various publications.  
 11 You weren't really looking at how it correlated with AMPs.

12 THE WITNESS: Well, I did look at those AMPs that  
 13 I had, and I did find that, for instance, this Teva NDC here  
 14 had an AMP that was about -- sorry, go ahead.

15 THE COURT: And which Teva were you just pointing  
 16 to?

17 THE WITNESS: The Teva direct price of .0989

18 THE COURT: Right, because that was the .03.

19 THE WITNESS: Yes, about --

20 THE COURT: A third.

21 THE WITNESS: Right.

22 THE COURT: So what you don't know is, if you were  
 23 to correlate this all with AMPs, whether or not, A, the  
 24 agency did that, or, B, if we were to do that, you would say  
 25 it would be guessing as to what they would have done with

<p style="text-align: right;">Page 30</p> <p>1 that?</p> <p>2 THE WITNESS: Well, in particular because there</p> <p>3 are clearly other data that they are relying on that you</p> <p>4 cannot tell from here just from published prices, you cannot</p> <p>5 tell what it is they were relying on to say, "This is not</p> <p>6 the right data, this is not the right data. This is the</p> <p>7 right --"</p> <p>8 THE COURT: So when this was asked, what did she</p> <p>9 say?</p> <p>10 MR. BUEKER: This? Your Honor, again, she said</p> <p>11 she was balancing two competing --</p> <p>12 THE COURT: But how did she come up with this? Is</p> <p>13 there a formula? Did she throw up a coin in the air, and if</p> <p>14 it's heads, it's No. 6, and tails it's the bottom? What did</p> <p>15 she do?</p> <p>16 MR. BUEKER: I think the testimony in the record,</p> <p>17 your Honor, is, they called manufacturers, they called</p> <p>18 wholesalers. There is no dispute -- whether or not she</p> <p>19 actually looked at AMP, there's no dispute that CMS had --</p> <p>20 THE COURT: Excuse me, excuse me. Did she say she</p> <p>21 looked at the AMP?</p> <p>22 MR. BUEKER: She did not, your Honor.</p> <p>23 THE COURT: She said she didn't look.</p> <p>24 MR. BUEKER: She said she did not look at the AMP.</p> <p>25 But they certainly had -- and there's an instance later --</p>	<p style="text-align: right;">Page 32</p> <p>1 ignore a lot of NDCs, some a fewer NDCs, big NDCs, small</p> <p>2 NDCs. The gap between where they could have been and where</p> <p>3 they will actually choose the FUL can be very big, smaller.</p> <p>4 It's very, very variable.</p> <p>5 However, the one thing that is systematic is, they</p> <p>6 go up. They set the FUL higher than 150 percent.</p> <p>7 THE COURT: So you're saying, of these nine drugs</p> <p>8 and these 31 NDCs, not once do they go to the bottom number?</p> <p>9 THE WITNESS: In only two cases out of 31 FULs do</p> <p>10 I find the situation where a FUL was set at the lowest</p> <p>11 published price, and during the period in which the FUL was</p> <p>12 in effect, there were no published prices that appeared that</p> <p>13 could have caused that FUL to be lower. In every other, 29</p> <p>14 cases out of 31, your Honor, either there was a lower price</p> <p>15 available at the time it was set, or during the time the FUL</p> <p>16 was in effect; and very often for a very substantial portion</p> <p>17 of that period during which the FUL was in effect, you had</p> <p>18 lower published prices that could have brought the FUL much</p> <p>19 lower, and CMS elected not to do it.</p> <p>20 So I guess going back to your question, what I</p> <p>21 conclude from this is that -- you know, I'm assuming that</p> <p>22 they're doing their jobs, and their objectives I know are</p> <p>23 twofold.</p> <p>24 THE COURT: Well, it's a legal question. They</p> <p>25 seem to be violating the regulations.</p>
<p style="text-align: right;">Page 31</p> <p>1 THE COURT: We can argue this at the motion later.</p> <p>2 So part of your analysis is -- you essentially</p> <p>3 didn't look at AMPs or any correlation. You're just simply</p> <p>4 saying it's not clear why they would pick any particular</p> <p>5 price because you have to know about that price at that</p> <p>6 point in time and that regulator, and there's no regulation</p> <p>7 or policy or practice that would help us?</p> <p>8 THE WITNESS: I think it goes a little beyond</p> <p>9 that, your Honor. I think it goes a little beyond that in</p> <p>10 the sense that -- and perhaps I should just summarize my</p> <p>11 results so I can put this in sort of some context, but I'm</p> <p>12 happy to just give you the headline right now, and then we</p> <p>13 can talk about it more in detail.</p> <p>14 THE COURT: Do you teach as well?</p> <p>15 THE WITNESS: I have and sometimes do.</p> <p>16 THE COURT: I just see you in teaching mode.</p> <p>17 (Laughter.)</p> <p>18 THE COURT: That's okay, it's a tutorial.</p> <p>19 THE WITNESS: I think what I conclude, based on</p> <p>20 having looked at these in great detail, these 31 FULs, and</p> <p>21 having reviewed the testimony and the documents from CMS, is</p> <p>22 that they deviate from this simple rule of 150 percent of</p> <p>23 the lowest published price very, very systematically, in the</p> <p>24 sense that the deviation happens a lot. The manner in which</p> <p>25 they deviate is extremely variable. As I've said, they will</p>	<p style="text-align: right;">Page 33</p> <p>1 THE WITNESS: Well, except that as I view it as an</p> <p>2 economist --</p> <p>3 THE COURT: As a lawyer, they're violating the</p> <p>4 regulation, right? There may be good economic reasons for</p> <p>5 doing it; they're just violating the regulation.</p> <p>6 THE WITNESS: Right, and I'm not a lawyer, your</p> <p>7 Honor. But as an economist, I can see that if you have a</p> <p>8 mandate and one of your objectives is to insure access, that</p> <p>9 would certainly explain why you were going above where your</p> <p>10 regulation tells you to be, because you're certainly not</p> <p>11 doing it to save costs. And if you have two objectives,</p> <p>12 that's the objective that's operational and causes you to go</p> <p>13 above. And the factors that cause you to go above are</p> <p>14 factors that are clearly extraneous to the published</p> <p>15 price -- that's my point -- because you cannot predict from</p> <p>16 the published price how they'd go up in any particular case.</p> <p>17 THE COURT: Is someone here from the federal</p> <p>18 government?</p> <p>19 MR. FAUCI: Jeff Fauci here with the Department of</p> <p>20 Justice, your Honor.</p> <p>21 THE COURT: Good. Don't leave, okay?</p> <p>22 (Laughter.)</p> <p>23 THE COURT: Thank you. Are you involved with the</p> <p>24 AWP case, or they just sent you up here?</p> <p>25 MR. FAUCI: No, I'm with the U.S. Attorney's</p>

1 office upstairs, and I'm involved with working on the cases  
2 against Dey and Roxane.

3 THE WITNESS: There was just one other chart I  
4 wanted to go over quickly, your Honor, which was another  
5 FUL, a FUL for Lorazepam 1-milligram pill that was based on  
6 prices published in April, 1998, and it was in effect from  
7 September, '98, to December, 2000. And the only reason I  
8 want to put this up and mention this is that again you have  
9 a FUL that was set at .6684.

10 MR. BUEKER: This is Slide 18, your Honor.

11 THE COURT: Well, the actual FUL that was set was  
12 what?

13 THE WITNESS: .6684. It's at the very top, your  
14 Honor, in the second line of the heading.

15 THE COURT: Okay.

16 THE WITNESS: And once again there were a variety  
17 of lower NDCs, lower-priced NDCs available on which to set  
18 the FUL. And this goes to the question you were asking,  
19 your Honor. There's a cluster of NDCs here with WACs around  
20 2 cents or less, which would have yielded FULs in the range  
21 of 2 to 6 cents, just reading down the column of the implied  
22 FUL. CMS elects to set a FUL at 66 cents, almost 67 cents.

23 And the final striking thing about this is that  
24 whatever price CMS used in triggering this FUL -- in other  
25 words, whatever price it went and multiplied by

1 150 percent -- is not among the published prices, and I did  
2 a pretty exhaustive search, your Honor.

3 So this is a case where CMS set a FUL apparently  
4 not using -- even though there were, you know, thirty or  
5 forty published prices to choose from, used a price that was  
6 not in any of the published prices. And the question that  
7 you had asked earlier I think is partially illuminated by  
8 this slide about the variation between where they could have  
9 gone and where they actually chose to go.

10 THE COURT: Okay. And, once again, you don't know  
11 the AMPs for any of these, right?

12 THE WITNESS: No. I don't believe I have the AMPs  
13 for the -- I may have some of them, but I haven't looked at  
14 them, your Honor.

15 MS. CICALA: They are in the record, if your Honor  
16 is interested.

17 THE COURT: Do you know that there were so many  
18 boxes that were rolled into this office that we actually had  
19 to get a separate storage room for them? So I will not be  
20 rooting around in the records.

21 MS. CICALA: What I mean to say, your Honor, is, I  
22 could hand them up to the Court if you'd like to see them.

23 THE COURT: That I would love.

24 MS. CICALA: Thank you.

25 THE COURT: All right. They're actually sitting,

1 it's like a vault from Raiders of The Lost Ark, you know, in  
2 a back storage room. So, I mean, if it's not flagged in a  
3 brief, we're just not going to get to it.

4 BY MR. BUEKER:

5 Q. Now, Dr. Addanki, you've shown the Court a couple of  
6 examples. Are these in any way unique?

7 A. No. I did the same kind of analysis for all 31 FULs,  
8 your Honor. And, as I said, the qualitative nature of the  
9 departures from picking 150 percent of the lowest published  
10 price varied depending on which FUL you're looking at, but  
11 in the overwhelming majority of cases, they could have set  
12 lower FULs.

13 Q. I know you started to do this before, but would you  
14 just quickly summarize for the Court your observations, the  
15 results of your analysis for all 31 of those FULs.

16 A. I'd be happy to, and I'm going to try to get the slides  
17 to work as well.

18 This is really just what I had said to you  
19 earlier, your Honor, that for 23 of the FULs, at the time  
20 the FUL was set, there were lower published prices that CMS  
21 could have used that it chose not to.

22 THE COURT: So it's 23 out of the 31?

23 THE WITNESS: At the time the FUL was set, there  
24 were already lower published prices available.

25 THE COURT: So the other eight were at rock

1 bottom?

2 THE WITNESS: No, that's not quite it, your Honor.  
3 For six, it is the case that at the time the FUL was set,  
4 the FUL was in fact based on the lowest price available at  
5 the time the FUL was set. For two of the other eight, it's  
6 not clear what the basis was for the FUL that was chosen;  
7 and for 23, there were lower prices available at the time  
8 the FUL was set.

9 THE COURT: For how many was it the second to  
10 lowest? You said at least one lower price. Do you  
11 remember?

12 THE WITNESS: I haven't got to that.

13 THE COURT: Was it a handful?

14 THE WITNESS: This typically --

15 THE COURT: I mean, you gave me some which are  
16 just amazing, but --

17 THE WITNESS: Yes, it depends on how many --

18 THE COURT: -- do you view this as one tail end of  
19 it?

20 THE WITNESS: It depends on how many NDCs there  
21 are just generally. So if there are only a handful of NDCs  
22 at all for the product, then, unsurprisingly, if you're  
23 going to get lower ones, you're going to get one or two.  
24 But there are drugs for which there are dozens of NDCs with  
25 lower prices, and in those cases you have a lot of lower

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1 NDCs.

2 THE COURT: So do I have this very helpful chart  
3 for every single one of the 31 NDCs?

4 THE WITNESS: You don't have it for literally  
5 every single one. The presentation has about seven or eight  
6 of them, your Honor, which we put in there just in case you  
7 wanted to see them. But there are tables, which I believe I  
8 have submitted in my declarations and affidavits, that show  
9 the number of lower NDCs available for each of the FULs in  
10 effect.

11 MR. BUEKER: Your Honor, so you don't have to  
12 become Raiders of The Lost Ark, why don't we have delivered  
13 to you a complete set of the arrays.

14 THE COURT: That would be useful. Thank you.

15 THE WITNESS: And in the second part that I've  
16 already mentioned to you, your Honor, was that while the FUL  
17 was in effect, in 29 out of the 31 cases, lower prices were  
18 published that could have prompted a lower FUL, and CMS  
19 elected not to do it.

20 Q. Now, the Court asked you earlier whether there was  
21 anything systematic in the way you observed CMS departing.  
22 Was there?

23 A. The answer is "yes" and "no." As I've said, when they  
24 depart, they only depart in one direction; it's going up.  
25 But the manner in which they depart, by how much they

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1 depart, by how many NDCs they depart is entirely variable.

2 Q. And you said earlier that you reviewed the CMS  
3 testimony and documents in this case, correct?

4 A. Yes, I did.

5 Q. And based on your analysis of the data and your review  
6 of that testimony and the other evidence that's in the  
7 record, what conclusions did you reach as an economist about  
8 how in practice CMS set FULs?

9 A. Well, as I said, your Honor, it was clear that rather  
10 than just rely on this regulation, CMS was relying on market  
11 intelligence and was exercising its judgment on a  
12 case-by-case basis to get the FUL to the right level, what  
13 they thought would be the right level, based on all the  
14 intelligence they had at their disposal, to balance these  
15 two cost and access objectives, which are potentially  
16 conflicting objectives.

17 THE COURT: So suppose everybody on this list  
18 reported something truthfully in terms of what a real  
19 wholesale acquisition cost is, do you have any basis for  
20 knowing one way or another what would have happened to the  
21 price?

22 THE WITNESS: I think we have a couple of  
23 important indicators as to what would have happened to the  
24 price. I think one important indicator we have is that when  
25 you see that they are doing this time after time after time,

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1 and you know that they're getting intelligence from outside,  
2 your first -- well, let me put it this way, your Honor: I  
3 would expect that if you've got these two objectives, you're  
4 only going to take the price as high as you feel you need to  
5 to meet your --

6 THE COURT: Suppose everybody on -- I don't know  
7 if it's true or not, but suppose absolutely everybody on  
8 this list is lying about the price, and you forced everyone  
9 to tell the truth, so everyone had to do AMP, and I were to  
10 go down this list, and everyone would do the AMP.

11 THE WITNESS: Right.

12 THE COURT: They may well still do this, I don't  
13 know, fudge-like effort at what it would be, but wouldn't it  
14 all start at a lower point?

15 THE WITNESS: I think, actually, we have the  
16 perfect natural experiment for that, your Honor.

17 THE COURT: Which is?

18 THE WITNESS: Which is, when there was a proposal  
19 to base the FUL on the AMP, you will recall, your Honor,  
20 that they didn't set it at 150 percent, even for the  
21 proposal. It was set --

22 THE COURT: Who proposed?

23 THE WITNESS: CMS proposed -- there was a proposal  
24 that CMS would set the FULs based on --

25 MR. MONTGOMERY: It's actually a Congressional

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1 statute, the Deficit Reduction Act of 2005.

2 MR. BUEKER: Mandated CMS do this.

3 THE COURT: That's when they finally did it.

4 MR. BUEKER: Well, no, they didn't do it because  
5 it was enjoined by a Federal District Court because it  
6 created access issues.

7 THE COURT: That was that one court --

8 MR. BUEKER: It's still enjoined. Congress has  
9 said --

10 THE COURT: It's not appealed?

11 MR. BUEKER: No. CMS decided not to appeal that,  
12 your Honor.

13 THE WITNESS: Your Honor, the --

14 THE COURT: Oh, the guy from Justice, I'm going to  
15 be asking you questions.

16 (Laughter.)

17 THE WITNESS: You will recall, your Honor, the  
18 proposal was for 250 percent of AMP to be used rather than  
19 150 percent, and --

20 THE COURT: It's actually beyond -- I haven't  
21 spent much time with this because it was post- --

22 THE WITNESS: Oh, okay, okay. The proposal was  
23 that the FUL should be based on 250 percent of the lowest  
24 AMP, and the OIG and GAO independently conducted studies of  
25 how --



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1 THE COURT: But this is after my time period,  
2 right?

3 Q. But, Dr. Addanki, is there anything in your analysis  
4 that would suggest that the same kinds of relationships that  
5 held after the period wouldn't have held during the period?

6 A. The relationships haven't changed very much, your  
7 Honor, between transaction prices and list prices. The  
8 basic nature --

9 THE COURT: Let's say they would have done  
10 250 percent of AMP, let's say, where would that have -- and  
11 I don't know if we were to do the math -- have you done out  
12 the math? Would that have ended up with higher prices?

13 THE WITNESS: At 250 percent of AMP, what the  
14 studies found was that for the top 25 Medicaid-reimbursed  
15 drugs, 19 out of the 25 drugs would end up with FULs that  
16 were below pharmacy acquisition cost. So those FULs  
17 couldn't work as a matter of what the FUL was trying to  
18 achieve because they were going to be below; the pharmacy  
19 was going to be underwater in every prescription. And at  
20 150 percent -- I've done the math -- at 150 percent, 24 --

21 THE COURT: On these 31.

22 THE WITNESS: Okay, the OIG didn't study these 31  
23 FULs.

24 THE COURT: All I'm asking is, did you look at  
25 these 31? If you were to take AMP and you did, let's say,

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1 250, or whatever it is you think they might have done, would  
2 that have ended up with higher or lower FULs? Did you do  
3 that math?

4 THE WITNESS: I think I've already shown you for  
5 this Teva case, for instance, you would certainly get a  
6 lower FUL if you based it on AMP because the AMP is a lower  
7 price. The AMP is a price net of all discounts. It's a  
8 manufacturer's net price. The question is, would CMS have  
9 set that FUL, given that that FUL would not have covered a  
10 pharmacy's acquisition cost for the drug? Right, that's the  
11 market intelligence we're talking about as to whether a FUL  
12 can actually be set at that level, or if that just wouldn't  
13 fly as a matter of what the FUL is supposed to achieve.

14 Q. You've used the term "market intelligence" a couple of  
15 times. What do you mean?

16 A. Well, of course, I understand the discussion about  
17 AMPs, but CMS has had the AMPs since 1991. They specify how  
18 the AMPs should be calculated, and they have them. They  
19 have --

20 THE COURT: But do you know as a matter of  
21 practice that people who are setting these prices feel as if  
22 they have access to them in order to set the prices?

23 THE WITNESS: I don't know as a matter of what  
24 they think.

25 THE COURT: That's fine. That may be beyond what

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1 you looked at.

2 THE WITNESS: They also get information from  
3 pharmacies. They get information from manufacturers. They  
4 get information from wholesalers, distributors. So they get  
5 information essentially from the industry, the marketplace,  
6 as to what's going on out there with respect to the  
7 different drugs that are covered under Medicaid. So that's  
8 the marketplace intelligence that is completely over and  
9 above anything in the published prices.

10 Q. Now, Sue Gaston, who we spoke about earlier, provided a  
11 declaration in opposition to defendants' motion for summary  
12 judgment. Have you looked at that?

13 A. I have.

14 Q. And is what Ms. Gaston says in her declaration  
15 consistent with the conclusions that you've reached about  
16 how CMS in practice set FULs?

17 A. Yes, it is, your Honor, in the sense that Ms. Gaston  
18 does say exactly what I conclude, that she confirms that CMS  
19 exercised its discretion, judgment and discretion on a  
20 case-by-case basis.

21 She does talk a little bit about, you know, what  
22 she might have done in considering NDCs when setting the  
23 FULs. She never states it as a rule. She talks about what  
24 she might have done, so it doesn't give us much guidance on  
25 what they actually did or what they would have done. But I

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1 did evaluate whether, if you applied that as a rule, you  
2 would then explain, that would be a good model of what CMS  
3 actually did in these 31 FULs, and it isn't.

4 THE COURT: So just to refresh my recollection,  
5 what exactly did she say she would do?

6 THE WITNESS: She, if I remember right -- well,  
7 actually, I think we've got a slide on that, just because I  
8 couldn't remember the language.

9 MR. BUEKER: I believe it's Slide 32.

10 THE WITNESS: She says, "If the lowest WAC  
11 resulted in a FUL that was higher than at least three  
12 published WACs (including the WAC used to calculate the  
13 FUL), I would use that WAC to set the FUL. However, if the  
14 resulting FUL was not higher than at least three published  
15 WACs, I might use the next higher WAC."

16 Q. And did you look at the data and examine whether that  
17 rule was in fact followed?

18 A. To the extent that you interpret the "might have" kind  
19 of language as a rule, it wasn't followed, your Honor.

20 There are plenty of instances -- I think there were twenty  
21 instances where you could lower the FUL and still have a FUL  
22 that was higher than at least three published WACs.

23 THE COURT: Now, she's saying this is what you  
24 personally would do, or this was what the policy of the  
25 agency was?



<p style="text-align: right;">Page 46</p> <p>1 THE WITNESS: I think it's talking about what she</p> <p>2 personally might do.</p> <p>3 MS. CICALA: Your Honor, would you like a complete</p> <p>4 copy of her declaration? I have it here, because we've only</p> <p>5 heard an excerpt that omits obviously --</p> <p>6 THE COURT: I'm sure I have it somewhere. You're</p> <p>7 going to ask about it, right?</p> <p>8 MS. CICALA: Yes. Well, I'm not going to ask</p> <p>9 Dr. Addanki about it because I don't need to ask Dr. Addanki</p> <p>10 what Ms. Gaston said, but I can read what she said.</p> <p>11 THE COURT: I know I've just absolutely hijacked</p> <p>12 this thing.</p> <p>13 MR. BUEKER: No. No, this was meant for your</p> <p>14 benefit.</p> <p>15 THE COURT: How much longer do you have with him?</p> <p>16 MR. BUEKER: Let me just ask a couple of summary</p> <p>17 questions. Then I'll sit down, your Honor.</p> <p>18 Q. Have you reviewed the other summary judgment filings?</p> <p>19 A. Some of them.</p> <p>20 Q. And you're aware of the argument along the line of</p> <p>21 questions the Court was asking about that the plaintiffs</p> <p>22 seem to be advancing that if defendants had reported an</p> <p>23 entirely different lower array of published prices, CMS</p> <p>24 would have set a lower FUL. Did you notice that argument in</p> <p>25 the summary judgment filings you read?</p>	<p style="text-align: right;">Page 48</p> <p>1 tutorial and what happened, right?</p> <p>2 THE WITNESS: I understand, and I guess all I can</p> <p>3 really talk about is what inferences I can draw as an</p> <p>4 economist from what I see, and --</p> <p>5 THE COURT: That's more of an expert witness</p> <p>6 thing, so I think I'm going to stop you there. This has</p> <p>7 been very helpful having you actually go through the data.</p> <p>8 Is there anything else you need to ask? It's not</p> <p>9 like an expert opinion as opposed to a --</p> <p>10 THE WITNESS: No --</p> <p>11 THE COURT: I understand a tutorial is just sort</p> <p>12 of like what happened.</p> <p>13 MR. BUEKER: No, that's fine, your Honor. I mean,</p> <p>14 Ms. Cicala alluded to earlier the fact that this witness has</p> <p>15 done a critique of the plaintiffs' expert, Harris Devor.</p> <p>16 THE COURT: I'm not doing -- this is a tutorial.</p> <p>17 This should just be matter-of-fact literally what happened,</p> <p>18 and that's very helpful. And I understand you've given me</p> <p>19 an expert report for purposes of summary judgment, but I</p> <p>20 think it's starting to bleed into what's somebody's opinion.</p> <p>21 MR. BUEKER: Thank you, your Honor.</p> <p>22 THE COURT: Thank you.</p> <p>23 THE COURT: Although I was probably as guilty of</p> <p>24 it as you were, so, sorry.</p> <p>25 MR. BUEKER: Thank you, your Honor.</p>
<p style="text-align: right;">Page 47</p> <p>1 A. I believe I did, yes.</p> <p>2 Q. And do you as an economist have a reaction to that</p> <p>3 argument, particularly in light of what you've observed CMS</p> <p>4 having done in setting FULs?</p> <p>5 A. I do, and I think I've explained some of it, your</p> <p>6 Honor. I'll just quickly highlight it again. What I</p> <p>7 interpret the plaintiffs to be saying is, had the defendants</p> <p>8 reported transaction prices such as AMPs to the compendia,</p> <p>9 and the compendia published these AMPs in place of the list</p> <p>10 prices that they published, that CMS would have set the FULs</p> <p>11 at 150 percent of these prices, and therefore the FULs would</p> <p>12 have been lower. That's the general understanding I have of</p> <p>13 what the plaintiffs' theory is.</p> <p>14 And what I've shown, I think, is in situations</p> <p>15 where we can see time after time CMS passing over sometimes</p> <p>16 very big NDCs, in terms of sales and availability, that</p> <p>17 could have triggered lower FULs, and CMS was passing over</p> <p>18 those NDCs and electing to set FULs at a higher level, the</p> <p>19 idea that they would have set the FUL at probably a much,</p> <p>20 much lower level just doesn't make economic sense. The</p> <p>21 marketplace factors --</p> <p>22 THE COURT: At this point it's your argument.</p> <p>23 It's not a tutorial in the sense of -- let me just say this:</p> <p>24 Your arguments are very helpful and have some force. It's</p> <p>25 just this is what you're surmising as opposed to just a</p>	<p style="text-align: right;">Page 49</p> <p>1 MS. CICALA: Dr. Addanki can step down.</p> <p>2 THE COURT: Are you done? You don't want --</p> <p>3 MS. CICALA: No, I don't need Dr. Addanki to tell</p> <p>4 me what CMS did, and neither does the Court. So I can talk</p> <p>5 about the CMS testimony --</p> <p>6 THE COURT: Well, what are you going to ask? You</p> <p>7 just ask him questions if you want to.</p> <p>8 MS. CICALA: I have no need to ask Dr. Addanki</p> <p>9 questions at all. Thank you.</p> <p>10 THE COURT: All right, good-bye. Thank you.</p> <p>11 THE WITNESS: Thank you.</p> <p>12 (Witness excused.)</p> <p>13 MS. CICALA: In connection with the tutorial.</p> <p>14 THE COURT: This is all we're talking about is the</p> <p>15 tutorial. Do you want to put your doctor on in terms of the</p> <p>16 tutorial, your expert witness?</p> <p>17 MS. CICALA: Well, I will in a moment. I would</p> <p>18 like, if I may --</p> <p>19 THE COURT: To confer with the team?</p> <p>20 MS. CICALA: No. What I'd like to do is just</p> <p>21 explain to the Court a bit about the evidence that has been</p> <p>22 put into the record. And it's certainly understandable,</p> <p>23 given the volume, that the Court may not --</p> <p>24 THE COURT: I didn't.</p> <p>25 MS. CICALA: Fair enough.</p>

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1 THE COURT: In fact, truthfully, I wasn't really a  
2 hundred percent positive we would be arguing the motions  
3 today. I wasn't sure if it was going to be consumed with  
4 the tutorial.

5 MS. CICALA: Right. Well, I'm just going to pick  
6 up -- if I may confine my remarks to the issue of how the  
7 FUL was set and CMS discretion, there's very little --

8 THE COURT: You know what I would prefer to do,  
9 though?

10 MS. CICALA: Certainly.

11 THE COURT: I am certainly happy to have you do  
12 that, but just so I don't hold the witness over, you've now  
13 rested in terms of your tutorial?

14 MR. BUEKER: Yes, your Honor, we have.

15 THE COURT: Do you have anybody you want to put on  
16 for a tutorial? And then I'll let you both -- I think we're  
17 going to have plenty of time.

18 MS. CICALA: In terms of tutorial --

19 THE COURT: In other words, what happened. Do you  
20 disagree -- is he going to refute any of this?

21 MS. CICALA: No. Mr. Devor is here to offer  
22 opinion regarding defendants' actual WACs. He is not here  
23 to offer an opinion regarding what CMS did. He's just here  
24 to offer opinion regarding defendants' actual WACs.

25 THE COURT: So he's essentially for these 31 NDCs

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1 going to give me the AMP or some equivalent thereto?

2 MS. CICALA: He's calculated an alternative WAC,  
3 and then he has determined what a FUL would have been if any  
4 of those alternative WACs had been used by CMS. He's a  
5 forensic accountant.

6 THE COURT: According to the literal letter of the  
7 regulation?

8 MS. CICALA: That's correct.

9 THE COURT: Not according to the fudgy approach?

10 MS. CICALA: Well, we call it the discretion  
11 approach. Mr. Devor offers no opinion, nor should he --

12 THE COURT: How would he know?

13 MS. CICALA: -- on what CMS -- Mr. Devor is not  
14 here to opine on what CMS would have done with defendants'  
15 actual prices. CMS tells us, through their deposition  
16 testimony and Ms. Gaston's declaration which is submitted in  
17 connection with our motion, what CMS --

18 THE COURT: Oh, I see. So taking this  
19 Slide No. 32, he calculates a FUL?

20 MS. CICALA: Yes, Mr. Devor has calculated what a  
21 FUL would look like if it were based on any of defendants'  
22 actual WACs or based on their AMPs. He did both, your  
23 Honor.

24 MR. BUEKER: To answer your Honor's question  
25 directly, no, he doesn't do anything with regard to Slide 32

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1 or anything that Ms. --

2 THE COURT: You just said you didn't disagree with  
3 anything Addanki just said.

4 MS. CICALA: I said I didn't -- I did not  
5 disagree -- what I'm trying to --

6 THE COURT: Let me just ask you this. He says the  
7 agency did not follow its own regulation in many instances.

8 MS. CICALA: The agency did not apply the, quote,  
9 "simple rule" in a large number of circumstances.

10 THE COURT: Okay, that's point one.

11 MS. CICALA: CMS --

12 THE COURT: Point two, he says you couldn't figure  
13 it out, he says, what they would do because they essentially  
14 did market research and would pick some other number,  
15 sometimes a real number, sometimes a fictional number.

16 MS. CICALA: Disagree.

17 THE COURT: You disagree with that?

18 MS. CICALA: Yes, and so does CMS. CMS would  
19 object to that.

20 THE COURT: So you disagree with that. And for  
21 that, you're relying on what Ms. Gaston says, right?

22 MS. CICALA: Yes, Ms. Gaston and Ms. Sexton and  
23 other CMS -- well, those are the two primary CMS witnesses,  
24 yes.

25 THE COURT: So what do you believe was the rule of

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1 thumb according to policy that CMS testified about?

2 MS. CICALA: Ms. Gaston tells us what the rule of  
3 thumb is, and what Ms. Gaston tells us is that she would  
4 look at the array of prices that was presented to her  
5 through the FULs printout. We can use the Clonazepam  
6 example, okay? And, first, she would examine whether the  
7 lowest price was an outlier; in other words, here it just  
8 appeared, some whacky number that wasn't in connection with  
9 the rest.

10 THE COURT: No pun intended.

11 MS. CICALA: If it was, she would ignore the  
12 outlier, and then she would look at the next lowest price.  
13 And this is in her declaration which is consistent with her  
14 testimony at deposition. She was deposed for more than one  
15 day.

16 If setting the FUL based on the next lowest price  
17 would result in a FUL that was higher than a few other WACs,  
18 then she would view that FUL as reasonable and not creating  
19 access issues, and the FUL would be set at that point. If  
20 setting the FUL on the next lowest price did not result in a  
21 FUL that was higher than two WACs, she might move up to the  
22 next lowest price and the next, and so forth.

23 THE COURT: All right. So assume for a minute  
24 you're roughly accurately describing what she said, is that  
25 what your expert did?

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<p>1 MR. BUEKER: Yes.</p> <p>2 MS. CICALA: What our expert --</p> <p>3 THE COURT: Because that would be useful.</p> <p>4 MS. CICALA: Well, what our expert -- that's a</p> <p>5 damages question, your Honor.</p> <p>6 THE COURT: Well, no, it's also a --</p> <p>7 MS. CICALA: Here's where we morph, if I may</p> <p>8 please finish --</p> <p>9 THE COURT: Yes.</p> <p>10 MS. CICALA: Here's where we morph, I think, from</p> <p>11 tutorial to argument, but here is our fundamental point,</p> <p>12 your Honor, and you were essentially making the same point.</p> <p>13 The array in front of CMS was comprised of false prices in</p> <p>14 an overwhelming majority of cases. Not every single WAC was</p> <p>15 false. Even some of defendants' WACs when we compare them</p> <p>16 to their AMPs were accurate or close to accurate, but</p> <p>17 overwhelmingly they were false, your Honor. And so the</p> <p>18 snapshot that CMS was looking at when it set the FUL did not</p> <p>19 reflect reality. Things that looked like outliers may not</p> <p>20 have in fact been outliers if the truth had been told.</p> <p>21 THE COURT: You're doing great argument. I'm just</p> <p>22 trying to figure out whether I need to hear from your</p> <p>23 expert. What did he do?</p> <p>24 MS. CICALA: He calculated alternative WACs based</p> <p>25 on defendants' actual transaction prices, which is something</p>	<p>1 THE COURT: Do you want to put him on or not</p> <p>2 because I need to -- do you want him? Is he here?</p> <p>3 MS. CICALA: Yes, Mr. Devor is here and can</p> <p>4 explain his methodology to the Court and can address some of</p> <p>5 the criticisms that defendants have leveled against the work</p> <p>6 that he has done.</p> <p>7 THE COURT: Is it a tutorial that will help me</p> <p>8 understand the CMS methodology, which is all I'm doing here</p> <p>9 today?</p> <p>10 MS. CICALA: No. It's more in connection with our</p> <p>11 motion and to demonstrate the falsity of the defendants'</p> <p>12 published prices.</p> <p>13 THE COURT: Fine. I think it's conceded that if I</p> <p>14 say that a WAC has to be some sort of market-based price,</p> <p>15 that it's not going to track AMP in many -- in all 31? Is</p> <p>16 that true? Is that conceded that WAC isn't the same as AMP</p> <p>17 in every single -- I know you're not conceding it's false,</p> <p>18 but --</p> <p>19 MR. MONTGOMERY: That's correct, your Honor.</p> <p>20 AMPs, which of course are filed with CMS, and which, by the</p> <p>21 way, it's important, the testimony from Ms. Gaston is that</p> <p>22 they had access to AMPs. She didn't use them, but she had</p> <p>23 access.</p> <p>24 THE COURT: Well, that's a legal question.</p> <p>25 MR. MONTGOMERY: No, no, as a factual matter, she</p>
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<p>1 that defendants --</p> <p>2 THE COURT: And then did what with it?</p> <p>3 MS. CICALA: And then he presents what a FUL would</p> <p>4 have been if based on that alternative WAC.</p> <p>5 THE COURT: But he didn't go through this</p> <p>6 methodology that you say CMS went through?</p> <p>7 MS. CICALA: No, nor should he have as an</p> <p>8 accountant, your Honor. CMS tells us how they would have</p> <p>9 treated accurate prices. And for purposes of liability,</p> <p>10 what we can do and what we have done --</p> <p>11 THE COURT: So I don't need his stuff. Why would</p> <p>12 I need it?</p> <p>13 MS. CICALA: Well, you need it for the context of</p> <p>14 our motion because Mr. Devor's results are among the ways we</p> <p>15 demonstrate the defendants' published WACs were false. So</p> <p>16 he's necessary in connection --</p> <p>17 THE COURT: We know that.</p> <p>18 MS. CICALA: Pardon?</p> <p>19 THE COURT: What's the hard thing to figure out</p> <p>20 is, would it have made a difference?</p> <p>21 MS. CICALA: Well, certainly CMS tells us it</p> <p>22 would, and Ms. Gaston's declaration tells us it would.</p> <p>23 Ms. Gaston's declaration said --</p> <p>24 THE COURT: Do you want to put him on or not?</p> <p>25 MS. CICALA: I can -- well --</p>	<p>1 personally had access. That's the testimony.</p> <p>2 MS. CICALA: Your Honor, your Honor --</p> <p>3 THE COURT: Whoa. Make a decision right now. Do</p> <p>4 you want him on or off the stand?</p> <p>5 MS. CICALA: No.</p> <p>6 THE COURT: Because I'd like to take a break and</p> <p>7 then get into legal argument.</p> <p>8 MS. CICALA: That's fine, your Honor. In</p> <p>9 connection with the tutorial, no, I do not want him on.</p> <p>10 THE COURT: All right, we'll take our break. I'll</p> <p>11 see you at 3:30.</p> <p>12 (A recess was taken, 3:14 p.m.)</p> <p>13 (Resumed, 3:42 p.m.)</p> <p>14 THE COURT: Okay, are you going first?</p> <p>15 MS. CICALA: Yes. Thank you, your Honor.</p> <p>16 The plaintiffs have moved for partial summary</p> <p>17 judgment against the thirteen manufacturers at issue who</p> <p>18 manufactured the non-GCN drugs that we have examined. And</p> <p>19 it's a partial summary judgment motion because we've only</p> <p>20 submitted papers in connection with our claim under New York</p> <p>21 Social Services Law 145-b. New York Social Services</p> <p>22 Law 145-b provides that "It shall be unlawful for a person</p> <p>23 knowingly by means of a false statement to obtain or to</p> <p>24 attempt to obtain payment from public funds." That is the</p> <p>25 violation itself, your Honor, and that is the claim for</p>

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1 which we filed our motion.

2 The evidence that we have submitted to the Court,  
3 the record evidence, is that the thirteen defendants  
4 knowingly submitted, published, false WACs, and in the  
5 course of doing that, attempted to obtain payment from the  
6 public fisc, and that activity by itself means that they are  
7 liable for a violation under 145-b. Relatedly, your Honor,  
8 our charge here from July --

9 THE COURT: Do you have to prove that it caused  
10 damage?

11 MS. CICALA: Well, certainly there's a causal  
12 nexus between their activity and the result, and that goes  
13 to Section 2 --

14 THE COURT: When you say that, to be clear, you  
15 agree that you have to prove that it caused injury?

16 MS. CICALA: No. I have to prove that their false  
17 statement was connected to the claim. Let me read  
18 Section 1(b), okay? "For purposes of this section,  
19 'statement or representation' includes but is not limited  
20 to: a claim for payment made to the state, a political  
21 subdivision of the state, or an entity performing services  
22 under contract to the state," et cetera, et cetera, or "an  
23 acknowledgment, certification, claim, ratification or report  
24 of data --" that's the relevant provision for us -- "which  
25 serves as a basis for a claim or a rate of payment."

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1 And this is the section that defendants have  
2 focused on, your Honor. And plaintiffs' position is that  
3 defendants' submission of false WACs indisputably affected  
4 where the FUL was set by CMS. The basis of the claim at  
5 issue here was the FUL, and therefore there's obviously a  
6 connection between defendants' pollution of the array of  
7 prices that CMS had in front of it and the FUL that was set.

8 So while we do not agree there's a causation in  
9 terms of damage, in terms of establishing the violation, we  
10 agree there must be a connection between the false report  
11 and the basis of the claim. And given that here the basis  
12 of the claim was the FUL and our position is that the FUL  
13 was false because of defendants' submission of false prices,  
14 we believe that we have the causal nexus here.

15 It's a slight distinction from the causation  
16 requirements the defendants are talking about, but certainly  
17 we acknowledge that there has to be a relationship between  
18 the false WAC and the basis of the claim, and, again, the  
19 basis of the claim was the FUL.

20 What plaintiffs have submitted by way of record  
21 evidence to demonstrate the falsity of defendants' WACs are  
22 an assortment -- we have an assortment of materials. First  
23 of all, we have alternative WACs calculated by Mr. Devor  
24 which demonstrate that the published WACs of defendants were  
25 false, and we also have the defendants' AMPs. And we have

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1 submitted evidence of both to your Honor in respect to all  
2 defendants for all of the drugs at issue.

3 THE COURT: What if you can prove that it was  
4 knowing, and that it was material, and it was a false  
5 statement, and it had a nexus to the claim, but there's no  
6 possible way of figuring out --

7 MS. CICALA: The damage.

8 THE COURT: -- three times the amount by which any  
9 fee is falsely overstated?

10 MS. CICALA: Well, we spent a fair amount of time  
11 thinking about that because obviously plaintiffs' objective  
12 on the hearing is to obtain a declaration of liability for  
13 violation of this provision. Secondly, 145-b has  
14 essentially a liquidated damages clause, which is our  
15 starting point for calculating what is the impact --

16 THE COURT: But it's not like the federal False  
17 Claims Act where you get X amount of dollars per false claim  
18 as an alternative.

19 MS. CICALA: No, we don't see that in the statute,  
20 your Honor. What 145-b-2 provides is that for any  
21 violation, the district or the state shall have a right to  
22 recover civil damages equal to three times the amount by  
23 which any figure is falsely overstated.

24 Now, the good news is, for the moment, because we  
25 have enough on our plates here today, that we don't need to

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1 answer the question of how we're going to resolve damages  
2 before agreeing that we have established a violation on the  
3 basis of the submission of the false prices. And if I may,  
4 I want to revisit a little bit about the impact of the  
5 false --

6 THE COURT: What if there's no possible way of  
7 figuring out damages?

8 MS. CICALA: Well, there is in fact, your Honor,  
9 and in general the way to do it would be to look at what FUL  
10 was set in the false world based on the false array that had  
11 been created versus what the FUL would have been if  
12 defendants had reported accurate prices, and that is the  
13 starting point for an evaluation of damages.

14 Now, the question then becomes, how do you measure  
15 each individual defendants' damages in connection with their  
16 prices? And the answer to that is admittedly somewhat  
17 complicated, but it is doable. And certainly the fact that  
18 it's complicated, at least under New York law, doesn't mean  
19 that we don't give it a try or that we find that they're not  
20 liable for the violation in the first place. There's  
21 questions of whether the defendants should be held joint and  
22 severally liable for the damage. That's something to be  
23 explored. There's also perhaps --

24 THE COURT: Have you sued everybody who had a  
25 therapeutic equivalent with a false WAC?



1 MS. CICALA: All that's at issue on this motion,  
2 your Honor, are thirteen defendants and their pricing  
3 practices. We have not sued everybody. And as we go  
4 through the record evidence, the fact is that there are  
5 certainly occasions where the defendants, the true WAC or  
6 the actual WAC and their AMP are close to what they  
7 reported. And in such events, there may be good reason --  
8 well, there's no liability in that case.

9 But the interesting question for us, or among them  
10 with respect to damages, what do we do with the defendants  
11 whose prices were ignored? Because CMS did, Ms. Gaston did  
12 indisputably, because of her access concerns, overlooked  
13 sort of the low-flying WACs; and when presented with the  
14 true array, she may well have done the same. And plaintiffs  
15 certainly would be prepared to sort of live and die by what  
16 Ms. Gaston did before and what it would have done in a  
17 truthful world. And perhaps the --

18 THE COURT: Why is she so critical? Who was she?

19 MS. CICALA: She set the FULs from --

20 THE COURT: Who was she?

21 MS. CICALA: -- the early '80s until -- hang on.  
22 She set the FULs for a twelve-year period, so for the  
23 majority of time at issue in our case, Ms. Gaston set the  
24 FULs.

25 THE COURT: Is she a high-level person or a

1 reasons. The issue is that the world in which CMS was  
2 operating at the outset was not an accurate world. And as  
3 your Honor was alluding to earlier, and if I may just pick  
4 up on this thread, the arrays of prices that CMS would have  
5 been looking at would have been an entirely different array  
6 had defendants reported accurate prices. And Ms. Gaston in  
7 fact I think provides the information that your Honor was  
8 alluding to earlier as well. She says, "If alternative  
9 prices had been presented, I would have considered them, and  
10 the FUL likely would have been lower." And in her  
11 declaration, Ms. Gaston, if I may hand up a copy, in her  
12 declaration, Ms. Gaston specifically addresses two drugs at  
13 two points in time when CMS did set -- may I approach?

14 THE COURT: Yes.

15 MS. CICALA: -- when CMS did set the FUL,  
16 Metoprolol and also cefadroxil. And what Ms. Gaston says  
17 is -- plaintiffs provided Ms. Gaston with an alternative  
18 array of prices that was populated by the alternative WACs  
19 calculated by Mr. Devor and then a different array populated  
20 with the defendants' AMPs, and asked Ms. Gaston, "Had you  
21 been presented with these arrays, what would you have done?"  
22 And in her declaration, Ms. Gaston describes what she would  
23 have done. And in both occasions, it's no surprise the FUL  
24 would have been lower than what it was. And in both  
25 occasions, a simple rule would not have been applied, but

1 low-level person?

2 MS. CICALA: Well, she was responsible for setting  
3 the FULs, and she was deposed -- she set the FULs from April  
4 of '91 to February of 2003, and she was deposed by  
5 defendants. The other two individuals who set the FULs were  
6 Cindy Bergen and Gail Sexton. Ms. Sexton also was deposed,  
7 and excerpts from their deposition testimony is in the  
8 record and explains their methodology, which was generally  
9 consistent. And Dr. Addanki accurately described that there  
10 were departures from the strict adherence to the simple rule  
11 where they took the lowest published price and marked it up  
12 150 percent.

13 THE COURT: Because the rule as worded on its face  
14 was violated, and so they basically tried to do justice  
15 basically.

16 MS. CICALA: Well, I mean, if you look at the  
17 inception of the FUL program, if you look at why the FUL --

18 THE COURT: I understand that. The rule says what  
19 it says.

20 MS. CICALA: Yes, and, listen, we're --

21 THE COURT: And it looks as if the plain language  
22 of the rule was violated, maybe for good reason, but it was  
23 violated.

24 MS. CICALA: Yes, I think the parties agree that  
25 CMS exercised discretion, and it did so for sound policy

1 nevertheless the FUL would have been lower.

2 It simply defies common sense that in a real world  
3 with accurate prices, the FUL would have remained where it  
4 was, and that's all that plaintiffs need to establish for  
5 the violation of 145-b. When we get into the damages  
6 questions, your Honor, the question would be to go through  
7 NDC by NDC and evaluate what the FUL would have been had the  
8 accurate prices been reported.

9 THE COURT: Under this methodology she outlined?

10 MS. CICALA: Yes.

11 THE COURT: And that's what your expert has not  
12 done?

13 MS. CICALA: No. That's not what we're here on  
14 today. We're here to demonstrate -- I mean, the genesis of  
15 the hearing today was, your Honor was reluctant to permit,  
16 you know, widespread discovery on all of the -- sorry.

17 THE COURT: I've got your argument, and it's  
18 pretty straightforward. Can I ask you about government  
19 knowledge for a minute?

20 MS. CICALA: Certainly.

21 THE COURT: So this is highly different from my  
22 other cases because in the other cases, as you know, it's  
23 published in a book, and by statute the government had to  
24 follow it, and there was no price-setting. Here CMS set the  
25 price, and CMS has the AMP.



1 MS. CICALA: Ms. Gaston --  
 2 THE COURT: So they have it. And it's very  
 3 different from all my other cases. It's a much closer  
 4 government-knowledge case. So I'd like -- did she say she  
 5 looked at them?  
 6 MS. CICALA: No, and I'll tell you, first of  
 7 all --  
 8 THE COURT: Did she say she had access to them?  
 9 MS. CICALA: Yes. She says in fact CMS received  
 10 the AMPs, but what she says --  
 11 THE COURT: But would she have gone and received  
 12 the AMPs to actually check for accuracy?  
 13 MS. CICALA: She testified that she did not do  
 14 that because they were not published prices, and so she  
 15 could not use them, and she understood they could not be  
 16 used for reimbursement.  
 17 THE COURT: So is that in this affidavit?  
 18 MS. CICALA: Yes, it is in the affidavit at  
 19 Paragraph 6: "Although CMS received average manufacturer  
 20 prices (AMPs) from manufacturers for the sole purpose of use  
 21 in the Medicaid drug rebate program, I understood that AMPs  
 22 were confidential, could not be used for reimbursement  
 23 purposes, and, in any event, AMPs were not prices published  
 24 in the national compendia and by law could not be used for  
 25 setting FULs. Therefore, I did not consider AMPs to set

1 FULs."  
 2 THE COURT: And would that have been true  
 3 throughout the period of time we're talking about?  
 4 MS. CICALA: Yes, your Honor. Yes, your Honor.  
 5 THE COURT: So the narrow legal question is,  
 6 unlike all my other cases, here the agency has the AMPs, has  
 7 full access to the AMPs, and the question is whether or not  
 8 that triggers the government-knowledge defense.  
 9 MS. CICALA: Well, you know, 145-b would say "no,"  
 10 your Honor, which makes --  
 11 THE COURT: Let me just make it clear. If she  
 12 herself had them sitting side by side as I asked him to do,  
 13 I would say that the government-knowledge defense was  
 14 triggered, okay, because if ever it were triggered, if she  
 15 actually had them and knew. What's the harder question is  
 16 where one part of the agency has it and the other part  
 17 doesn't, whether or not the knowledge of one program is  
 18 attributable to another. It's a harder question than I've  
 19 had in any of my other cases. It's much closer.  
 20 MS. CICALA: I understand. If I may be heard on  
 21 that just for a moment.  
 22 THE COURT: Is there a case on point?  
 23 MS. CICALA: Well, there -- 145-b shares many of  
 24 the attributes with standard False Claims Act cases. And,  
 25 you know, what's interesting here is, we don't have a

1 scenario here where the law is going to take us on a limb  
 2 that doesn't make any practical sense. Think of the  
 3 implications of the defendants' or AMP argument, that every  
 4 civil servant, including Ms. Gaston, would be charged when  
 5 being presented -- or any civil servant when being presented  
 6 with a claim is charged with determining the veracity of  
 7 that claim. The government could not function that way.  
 8 The onus is on the entity who's --  
 9 THE COURT: I'm just trying to understand. Just  
 10 back up for one minute. Is there a government-knowledge  
 11 defense under state law?  
 12 MS. CICALA: No, not to 145-b. There's no --  
 13 THE COURT: How do we know that?  
 14 MS. CICALA: From the plain language of the  
 15 statute. And there are no cases, there are no cases stating  
 16 that there is a government-knowledge defense.  
 17 THE COURT: Are there cases that say that they  
 18 follow the False Claims Act on the federal government claims?  
 19 MS. CICALA: Absolutely, and we've distinguished,  
 20 we've talked about them in our briefs, your Honor. And  
 21 certainly where you have a situation where there is an  
 22 agreement between the government and the person submitting  
 23 the claim, there's some sort of express agreement, in this  
 24 case it would look something like this: "Yes, we know your  
 25 WACs are false. Yes, we know how much they're false, and

1 we're going to use them anyway," which is essentially what  
 2 defendants' argument is, right?  
 3 THE COURT: Well, skip the agreement. Suppose  
 4 everything you just said, we know they're false, and then  
 5 they continue to use it.  
 6 MS. CICALA: We know they're false, we know how  
 7 much they're --  
 8 THE COURT: Subjectively, this woman Gaston  
 9 actually -- suppose you had that situation -- actually knew  
 10 they were false and then continued to use.  
 11 MS. CICALA: Look, if the government -- if the  
 12 government -- the government obviously can choose to conduct  
 13 itself on the basis of false data if it wants. The question  
 14 is, is it informed that the data is false? And Ms. Gaston,  
 15 there is no testimony that Ms. Gaston knew the WACs were  
 16 false. In fact, if you look at the record evidence put in  
 17 from the defendants in this case, your Honor, they took  
 18 twenty CMS depositions, twenty different witnesses over  
 19 twenty-eight days, and they don't have a stitch of evidence  
 20 that those witnesses believed the WACs to be false, not a  
 21 stitch of evidence from twenty witnesses. CMS, just like  
 22 the state Medicaid programs, your Honor, believed the WACs  
 23 were accurate, and that EAC lay somewhere between WAC and  
 24 AWP. That was the belief. As the years progressed and  
 25 knowledge came to the fore about the falsity of the WAC, you

1 see the reaction. You see CMS now endeavoring, or through  
2 Congress, to put in place different ways to set the FUL  
3 because the knowledge has developed, and now they know the  
4 WACs are in fact not true.

5 THE COURT: At what point is that?

6 MS. CICALA: It's consistent with your findings in  
7 Mylan, your Honor. You've got the Medicare Modernization  
8 Act in 2003 that for the first time defines WAC as a list  
9 price, okay. That's another fact indisputable, right? That  
10 definition had not been previously codified. There was  
11 not --

12 THE COURT: So might there be a different analysis  
13 between 2003 and 2005?

14 MS. CICALA: Yes, there very well might. There  
15 very well might. But what there is not is any record  
16 evidence that the government understood WACs to be false  
17 prior to that point. There simply is not, and, again, nor  
18 have defendants put it in front of your Honor. And you can  
19 look at how CMS was conducting itself in respect of the FUL-  
20 setting process to demonstrate that. You can look at the  
21 state Medicaid programs, the multi-state chart. I don't  
22 know if your Honor has seen the CMS multi-state chart.  
23 Every single state in the country is either WAC plus or AWP  
24 minus because everyone thinks the truth is somewhere in  
25 between.

1 THE COURT: No, they don't. It's unbelievable  
2 that there are still states in the United States of America  
3 operating off of AWP, and if they want to eat that money,  
4 they can eat it. I mean, it's extraordinary to me. So, I  
5 mean, at some point they've got to have some responsibility,  
6 but the question is what point that is.

7 MS. CICALA: I agree, I agree. I completely  
8 agree. There's no disputing that, your Honor. But the  
9 question is, what is that point, and what does the evidence  
10 show the knowledge to be? And defendants here, after all  
11 this testimony from CMS, they can't show knowledge of  
12 falsity of WAC. And instead they've submitted evidence to  
13 the Court --

14 THE COURT: Well, at some point before 2003, they  
15 must have known because the bill passed then, so they must  
16 have been submitting things to Congress. At what point did  
17 they --

18 MS. CICALA: Well, you know, in your Mylan  
19 decision, you start talking about murmurings of this in late  
20 2001 and 2002, and then you say certainly by '03. And the  
21 defendants have submitted some different evidence knowledge  
22 here, your honor, but it's of the same ilk. None of it  
23 demonstrates actual knowledge of the government that these  
24 WACs are completely decoupled from reality, which is --

25 THE COURT: Let's take your argument, which is an

1 excellent one, which is, all right, you have CMS, for a  
2 period of time for sure they believed WACs were truthful.  
3 That's why they moved off of AWP to WAC, but at some point  
4 it became clear that WACs weren't even good. So there's  
5 going to be a period of time where government knowledge, you  
6 don't have to go around ferreting, but at some point there's  
7 some sort of inquiry knowledge, they know, so why aren't  
8 they then going in and checking?

9 MS. CICALA: Well, if you study the testimony of  
10 the CMS witnesses, you see, as the years go by, there is  
11 more of an application of the simple rule as there is this  
12 recognition that what they're looking at may not actually  
13 reflect reality. So in the context of doing a damages  
14 analysis here, if we calculated damages based on what CMS  
15 did in the old world and then we take those same choices,  
16 even if they ignored some of the low WACs, and we import  
17 that into the true world, then we'll see as over time  
18 there's more of a selection of the lowest WAC.

19 THE COURT: Just help me through. What's the  
20 period of time where you would say there's absolutely no  
21 knowledge that anyone in the agency even had inquiry notice  
22 to look at AMPs?

23 MS. CICALA: Certainly through the end of 2002,  
24 your Honor.

25 THE COURT: All right, so you would say through

1 2002?

2 MS. CICALA: Yes, yes.

3 THE COURT: And then after that, there might be a  
4 disputed issue of fact, you would say. I'm just trying to  
5 understand.

6 MS. CICALA: You know, because what we have, in  
7 2004 the OIG does its first real report on how the FUL is  
8 working.

9 THE COURT: In 2003 we have the statute, so --

10 MS. CICALA: Right, that's right, we do. We do.

11 THE COURT: So, all right, I'll think about that  
12 one. Thank you.

13 MS. CICALA: And can I make one other small point  
14 on this array issue, your Honor?

15 THE COURT: Yes.

16 MS. CICALA: Absolutely true that the lower prices  
17 were ignored. There's no dispute on these facts, your  
18 Honor. But if you look at what Ms. Gaston -- if you look at  
19 what was done here, the array of prices range from 7 cents  
20 to 84 cents, and the WAC that was chosen was 16 cents. And  
21 if you look through the printouts that we have submitted in  
22 connection with our papers and if you look at the excerpts  
23 of the deposition testimony, you'll see that whatever was  
24 selected was always towards the low end of the array,  
25 always. So it simply defies logic, and it also would be

1 contrary to the CMS testimony, including the declaration, to  
 2 believe that if the prices represented in this array shifted  
 3 downward in the main, the FUL would remain the same or be  
 4 higher somehow. It's completely contrary to logic or the  
 5 CMS witnesses' testimony. And so that is why we feel quite  
 6 certain with our position, your Honor, that defendants'  
 7 false prices create a fictional universe that CMS had to  
 8 operate in, and the FUL was indisputably higher as a result.  
 9 And that, frankly, is all we need under 145-b for liability.

10 Damages is another day, and we look forward to  
 11 that hearing, and we look forward to expert reports to deal  
 12 with it because it can be addressed. But on the liability  
 13 issue, your Honor, it's simply indisputable that by creating  
 14 this fictional array, the FUL was higher than it otherwise  
 15 would have been.

16 THE COURT: Okay, thank you.

17 MR. MONTGOMERY: Your Honor, let me go back to  
 18 where I think your Honor started earlier in the tutorial,  
 19 back to July 30 of 2007 when you actually issued the order  
 20 that led to this very hearing. And in that order, you  
 21 denied the defendants' renewed motion to dismiss, a motion  
 22 to dismiss which was based upon a public record in which we  
 23 told you CMS didn't comply with the FUL regulation. But  
 24 nevertheless you issued an order saying, well, we were going  
 25 to have a narrow, focused hearing on a test set of drugs

1 that would be agreed upon by plaintiffs and defendants. And  
 2 you said that "The plaintiffs have to allege and prove that  
 3 the defendants submitted false or inflated published prices,  
 4 which, if truthful, would likely have affected the FUL."  
 5 That's what we're doing here today because as Ms. Cicala  
 6 concedes, there is a causation requirement. She can parse  
 7 that language any way she wishes, but the fact is that for a  
 8 statement to be false, it has to be the basis of the FUL.  
 9 So you got it right.

10 THE COURT: But the tough point for me is, if  
 11 everybody in that list had reported a truthful WAC, isn't it  
 12 likely that the FUL would have been lower?

13 MR. MONTGOMERY: Absolutely not.

14 THE COURT: That's where I'm not sure. I'm not  
 15 sure you can figure out how much lower, but why not?

16 MR. MONTGOMERY: Well, I think several reasons.  
 17 First of all, we have an agency that, notwithstanding what  
 18 they published in the federal record, is applying a policy  
 19 judgment. We have done the most complete inquiry that we  
 20 have been able to accomplish in two years regarding that  
 21 policy-based system. It's a shadow system, your Honor, that  
 22 CMS was operating.

23 Contrary to what Ms. Cicala just told you about  
 24 our depositions of twenty CMS witnesses, that never  
 25 happened. We were allowed to depose two CMS witnesses. We

1 would have been glad to depose policy-makers, but we were  
 2 not given that choice. We were given Sue Gaston, who you've  
 3 suggested may be a relatively low-level employee.

4 THE COURT: Well, I have no idea who she is.

5 MR. MONTGOMERY: Well, she is the person in  
 6 charge, but she's clearly not a policy-maker. But she is  
 7 applying policy-based judgments, and she's doing it each and  
 8 every time they set a WAC. And as Dr. Addanki told you, in  
 9 most every instance, not every but in most every instance,  
 10 they ignore the rule. In every single instance, she makes a  
 11 policy judgment. Even if she picks, as she did twice, the  
 12 lowest published WAC, she makes a policy judgment that  
 13 that's an appropriate level at which the federal government  
 14 should establish the upper limit of reimbursement. And she  
 15 does that in every single instance on the basis --

16 THE COURT: If you take her description of what  
 17 she did, though, it wasn't like throwing a dart.

18 MR. MONTGOMERY: No.

19 THE COURT: She moves up from the bottom. So if  
 20 the bottom were much lower, isn't it fair to infer that the  
 21 ultimate price she would have set in the lower universe  
 22 would have been lower?

23 MR. MONTGOMERY: No -- well, let's step aside from  
 24 Sue Gaston. I don't know what Sue Gaston would have done.  
 25 It is clear that's not what CMS would have done because we

1 know that CMS has had quarterly AMPs from each of the  
 2 defendants since 1991. The period here starts in 1996.

3 THE COURT: But suppose you have an agency which  
 4 unfortunately operates out of silos.

5 MR. MONTGOMERY: Well, your Honor, there is --

6 THE COURT: No, no, just this is the narrow legal  
 7 question. This is the first time the government-knowledge  
 8 defense, in my view, has been fairly teed up, actually,  
 9 because here we actually have one agency that has both sets  
 10 of information, but one program is not talking to the other  
 11 program, so this is a much closer call than any of the other  
 12 cases I've had.

13 MR. MONTGOMERY: To that point, your Honor, we  
 14 have no evidence, you have no evidence that there are silos  
 15 here.

16 THE COURT: I have no evidence that anyone  
 17 actually talked.

18 MR. MONTGOMERY: Let me show you a piece of  
 19 evidence and put up on the screen a slide.

20 THE COURT: Do I have it?

21 MR. MONTGOMERY: Actually you don't have it.  
 22 Well, you do have it. It is Exhibit B to the defendants'  
 23 reply brief in support of our motion for summary judgment.  
 24 So what we have, and I concede that it's not a robust  
 25 record, but this is an agency that is trying to deny us

<p style="text-align: right;">Page 78</p> <p>1 access to information, your Honor. We have Sue Gaston  2 saying, "Yes, I had access to the AMPs," not that it was  3 siloed. That's her deposition testimony.  4 THE COURT: What does this mean, "Could you try  5 MDR again"?  6 MR. MONTGOMERY: Right, now, let me -- so we have  7 Sue Gaston's testimony. Now we have an e-mail, and an  8 e-mail from somebody we understand to be Sue Gaston's  9 superior named Larry Reed. And in connection with a drug  10 that I know your Honor is familiar with from another  11 context, Neurontin, several days prior to this e-mail --  12 THE COURT: Is this on-label or off-label?  13 MR. MONTGOMERY: -- several days prior to this  14 e-mail, the OIG issued a report regarding CMS's  15 administration of the FUL system. They mentioned the drug  16 Neurontin. This exchange concerns Neurontin. What Gail  17 Sexton, Sue Gaston's colleague, says is, "Well, gee, I'm not  18 sure we can set a FUL on Neurontin because there's a lack of  19 current information in the system." And Larry Reed says,  20 "Check again in the MDR." That's their AMP computer system.  21 "Are AMPs available?" He's essentially saying, can we use  22 AMPs?  23 THE COURT: So this is in January of 2005?  24 MR. MONTGOMERY: That's right. But, your Honor,  25 I'm not -- and I'm not trying to make a point that the</p>	<p style="text-align: right;">Page 80</p> <p>1 MR. MONTGOMERY: That's right.  2 THE COURT: But they didn't, and they didn't  3 actually know what they were.  4 MR. MONTGOMERY: No. What you have is that the  5 individual setting the FULs --  6 THE COURT: Fair enough.  7 MR. MONTGOMERY: -- did not access the AMPs, at  8 least the individual who's testified. Gail Sexton may well  9 have accessed the AMPs. Certainly Larry Reed is treating in  10 this 2005 instruction access to AMPs by these line employees  11 as a relatively routine matter.  12 But as a record point, your Honor, this is summary  13 judgment. We plainly have shifted the burden, in Celotex  14 terms, to the plaintiffs. They have the obligation under  15 your order to show that it's likely that CMS, if they had  16 had WACs published as AMPs, that it would have made a  17 difference. They can't show that, both because CMS always  18 had access to AMPs, and because when CMS actually looked at  19 Congressional direction at changing to an AMP-based system,  20 they couldn't do it. It's still being studied. And we can  21 give you all the chapter and verse you'd like on the  22 question, but just recently, in the last month, the judge in  23 the AMP/FUL case has amended his preliminary injunction to  24 permit AMPs to be disclosed to GAO so that they can conduct  25 a study to see whether 300 percent of AMP might work. So</p>
<p style="text-align: right;">Page 79</p> <p>1 timing is -- it's just that this is a clear administrative  2 communication within this agency that has made it very, very  3 difficult for the defendants to actually explain the truth  4 to this Court, the truth that we told you was plain on the  5 record.  6 THE COURT: I've got to go on the record that I've  7 got, which is --  8 MR. MONTGOMERY: That's right.  9 THE COURT: -- I think it would be fair to assume  10 that, based on what I've got, that the people who were  11 setting the FULs were not actually accessing the AMPs, but  12 they had access to them if they wanted to.  13 MR. MONTGOMERY: Exactly.  14 THE COURT: I think they felt they couldn't look  15 at them because they weren't published prices, but they  16 could have gotten access if they wanted to. The question  17 is, is that enough to trigger a government-knowledge  18 defense?  19 MR. MONTGOMERY: And, your Honor, they could have  20 changed the FUL system at any time they wished to an  21 AMP-based system. If you look at the so-called --  22 THE COURT: I understand all that, but as I  23 understand it, the only record I have is, they could have  24 gotten -- they could have received access to the AMPs if  25 they wanted to.</p>	<p style="text-align: right;">Page 81</p> <p>1 that when CMS tried this, they couldn't do it. So that's  2 all the evidence you need that in the real world, that a  3 full array of AMP-based prices, not just the defendants' but  4 everyone, could not have worked at 150 percent of AMP.  5 THE COURT: Is it a federal judge, I assume?  6 MR. MONTGOMERY: Yes.  7 THE COURT: Who?  8 MR. MONTGOMERY: Royce Lambert. And, you know,  9 it's been a well-litigated and hotly litigated case in which  10 we take note of the fact that the Department of Justice  11 decided not to take an appeal from that preliminary  12 injunction, in the face of reports from the GAO and the OIG  13 that this wouldn't work.  14 THE COURT: So suppose you had 300 percent of AMP,  15 would that still be lower than what --  16 MR. MONTGOMERY: You know, your Honor, would it be  17 lower? Yes, it would probably be lower than some of these,  18 but, again, that's a matter that's still the subject of  19 study. What the burden here is for the plaintiffs, because,  20 as I said, we have shifted it to them, they've got to show  21 that it's likely that in these instances between 1996 and  22 2005, that the agency actually would have taken the  23 published prices and would have published AMPs that we now  24 know, on the basis of published reports, could not have  25 worked. And as Dr. Addanki told you, you know, during the</p>



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1 period 2005 to 2008, there's no substantial difference in  
2 the economics of pricing in the pharmaceutical industry.

3 THE COURT: Part of the issue is that the whole  
4 system is perfused with problematic pricing. If truthful  
5 WACs had been published in the Blue Books, then is it likely  
6 that the pharmacies would have been paying less? So, in  
7 other words, we wouldn't have a crisis, or at least there  
8 would be a crisis at a lower level of magnitude.

9 MR. MONTGOMERY: Your Honor, I think that's  
10 entirely speculative. I don't think there's any evidence  
11 that the availability of AMPs in the post-perfect storm era,  
12 availability of ASPs, has made any difference to what  
13 pharmacies are actually paying. So I think I understand  
14 your question, it's a legitimate question, but it's --

15 THE COURT: I have no idea.

16 MR. MONTGOMERY: -- just not part of this record.  
17 And if the dramatic falloff that might be implied by  
18 plaintiffs' arguments all these years had occurred, I think  
19 that we would all know about it because it would be a big  
20 item of discussion nationally. It just hasn't occurred.

21 THE COURT: All right, well, you don't know  
22 either, so --

23 MR. MONTGOMERY: I don't know.

24 THE COURT: It's not part of this record.

25 MR. MONTGOMERY: It's not part of this record.

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1 THE COURT: All right, thank you.

2 MR. MONTGOMERY: Can I make one more point?

3 THE COURT: Yes.

4 MR. MONTGOMERY: When it comes to the Gaston  
5 affidavit, I think it's very important that your Honor apply  
6 to it a very exacting inquiry, and the reason is because if  
7 you lack back -- and I'm not suggesting you do because you'd  
8 have to become the Raiders of The Lost Ark -- but if you  
9 look back in the record, I think you'll find that the reason  
10 that you denied summary judgment, at least in part, is  
11 because the Department of Justice submitted an amicus brief  
12 to you, and that amicus brief said that FULs were set  
13 mechanically under the regulation. And what they told you,  
14 which certainly set up the basis for this order -- and they  
15 submitted the amicus brief just three or four weeks before  
16 you issued this order -- was not accurate. And then we  
17 fought for two years to get the discovery, and now we get  
18 this responsive affidavit. There is not a word in the  
19 affirmative papers supplied to you by these plaintiffs about  
20 Ms. Gaston. What you've got now is a responsive affidavit.  
21 And when you get a responsive affidavit on summary judgment,  
22 you need to look at it very carefully. If what they say  
23 about Ms. Gaston is accurate, then the affidavit is  
24 inconsistent with her testimony, and you should disregard it  
25 on that basis.

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1 Now, we don't think it is inconsistent.

2 THE COURT: Do I have her full deposition?

3 MR. MONTGOMERY: Yes. We have submitted -- I have  
4 it here, but we have also submitted as one of our summary  
5 judgment exhibits in one of those boxes a copy of it. I can  
6 certainly hand this one up to your Honor.

7 THE COURT: I actually would like that. It flags  
8 for me one of the problems in this case. I suppose you all  
9 feel like you need to paper it to death for an appeal,  
10 should one come, but it makes it unrealistic for me to even  
11 keep the materials in my office. I'm sure you have an  
12 office designated at your firms for this.

13 MR. MONTGOMERY: Yes.

14 THE COURT: And I'm wondering whether there's a  
15 way in the future to just flag, like you do at a hearing,  
16 which is lovely, just a few key things that I really sort of  
17 must read kind of thing, and the rest is just for my bedtime  
18 pleasure, you know. But it's useful to bring up just a  
19 couple of the key things, and I appreciate them at the  
20 hearings, and they're the kind of things I will sit down and  
21 read myself.

22 MR. MONTGOMERY: One more thing that I do want to  
23 point out to your Honor about Ms. Gaston because I think the  
24 plaintiffs have said here today, and I think you'll find  
25 when you get into this more deeply, that she becomes really

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1 the linchpin, the last gasp that they have to avoid summary  
2 judgment on causation grounds. And Ms. Gaston in her  
3 affidavit articulates this so-called three-WAC rule. And I  
4 won't go into exactly how it works except to say, and this  
5 is important, that Dr. Addanki in his report that he filed  
6 on June 30 -- I can give you a copy, and I can also give you  
7 the docket citation -- in Dr. Addanki's June 30 report, he  
8 takes the so-called three-WAC rule, and he applies it here  
9 to all of the NDCs at issue, and finds out it rarely was  
10 applied. And so --

11 THE COURT: Unfortunately for everyone in this  
12 room, doesn't that create a question of fact that I can't  
13 resolve here?

14 MR. MONTGOMERY: Not so, your Honor, because as I  
15 said --

16 THE COURT: She says one thing, he says another.

17 MR. MONTGOMERY: No, no, no. I think it's a  
18 matter of burden of proof, your Honor. I do not think that  
19 on this record the plaintiffs can possibly make out a case  
20 of causation. There is no dispute of fact. They haven't  
21 disputed what Dr. --

22 THE COURT: Does she testify about this so-called  
23 three-WAC rule?

24 MR. MONTGOMERY: She testifies about the three-WAC  
25 rule. All we're saying is, the three-WAC rule, even if



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1 she's testifying in good faith, even if she believes that  
2 the three-WAC rule is her mode of operation, she didn't tell  
3 us about it in her deposition, and in fact it --

4 THE COURT: I thought you said she did.

5 MR. MONTGOMERY: No, no, Gaston did testify in  
6 a -- she was deposed. So she's articulated a so-called  
7 rule, let's assume in good faith, that in fact isn't  
8 applied. That inconsistency, because she must have had  
9 Dr. Addanki available, you know, access to Dr. Addanki's  
10 information about how all of this worked, that inconsistency  
11 is something as a summary judgment matter that you ought to  
12 scrutinize. Witnesses can't come along in response in  
13 summary judgment and pose new issues, articulate new rules  
14 that are inconsistent with the facts, without explaining  
15 themselves.

16 THE COURT: I thought she was deposed.

17 MR. PALERMO: Your Honor, I'm sorry. Chris  
18 Palermo. Can I clarify?

19 THE COURT: Yes.

20 MR. PALERMO: Do you want me to try to clarify, at  
21 least? It's my understanding that Ms. Gaston did testify,  
22 but at her deposition did not mention the three-WAC rule,  
23 and that it was mentioned in her subsequent declaration.

24 MR. MONTGOMERY: Yes, that's my point, your Honor.  
25 She was deposed in this case. She did not mention the

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1 three-WAC rule. She then mentions the three-WAC rule in her  
2 affidavit. But, most importantly, regardless of when she  
3 mentioned it, the three-WAC rule, just like the FUL  
4 regulation, isn't applied. It doesn't work. And there's no  
5 dispute about it. So you've got --

6 THE COURT: You think she mentions it in the  
7 deposition?

8 MS. CICALA: Ms. Gaston's testimony in her  
9 deposition -- your Honor will read the deposition, I'm sure.  
10 The testimony in the deposition is entirely consistent with  
11 the declaration.

12 THE COURT: But does it refer to the three-WAC  
13 rule?

14 MS. CICALA: It refers to the procedure, which is  
15 the same procedure in the declaration, which is that she  
16 works her way up through the array to make sure that there  
17 are two WACs higher than the FUL that she sets.

18 THE COURT: And that's in the deposition?

19 MS. CICALA: Yes, and it's absolutely in the  
20 deposition. There's nothing inconsistent whatsoever between  
21 the approach applied --

22 THE COURT: So what you're going to do, you're  
23 going to just e-mail Mr. Alba the pages?

24 MS. CICALA: We will, we will. May I respond --

25 THE COURT: Just to make sure they know what

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1 you're referring to.

2 MR. MONTGOMERY: One more point.

3 THE COURT: Wait a minute, hold on. I tell you  
4 what, just let her finish her sentence and --

5 MS. CICALA: Thank you, your Honor very much.

6 THE COURT: Just on that point, and then I'll let  
7 you respond. So somebody could flip through the deposition.

8 MS. CICALA: There's nothing whatsoever  
9 inconsistent between the declaration and the deposition.  
10 What the declaration adds, your Honor, is that Ms. Gaston  
11 offers the exact information your Honor was referring to  
12 earlier: What would she have done were she presented with  
13 an array with accurate prices from these defendants?

14 THE COURT: But the way she calculated it is in  
15 the deposition?

16 MS. CICALA: Yes.

17 THE COURT: All right, thank you. Just finish up  
18 because it's getting late.

19 MR. MONTGOMERY: Your Honor, if you look at her  
20 affidavit, what she says throughout is, "I might have done  
21 A, I might have done B." When she gets to the three-WAC  
22 rule, she said, "If there were different prices --" she does  
23 not talk about an array -- she talks about one or two, or  
24 two, I guess -- and she says, "I would have considered them  
25 and would have used one of them to set the FUL, provided I

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1 was able to determine that the price was valid and the  
2 product was widely available in the marketplace as described  
3 above."

4 If you then look above or look at her deposition,  
5 what she's talking about is, she's going to do the market  
6 research that they did in every single instance. Medicaid,  
7 CMS here, your Honor, is like the PBMs that you called the  
8 800-pound gorillas. They have MACs. This is a MAC. The  
9 PBMs used AWP and WACs to set their MACs, but they also had  
10 market intelligence. You declined to certify a class. It's  
11 just a perspective point, your Honor. It's --

12 THE COURT: Just one last thing. Suppose I think  
13 it's likely that FULs would have been lower, but there's  
14 absolutely no possibility of figuring out what they would  
15 have been. Do you agree, putting aside the  
16 government-knowledge defense for a minute, do you agree that  
17 you don't have to get to the issue of whether it's even  
18 possible to calculate actual damages as part of this summary  
19 judgment motion? In other words, what if I found it's  
20 impossible to calculate actual damages, is that part of the  
21 cause of action at this point? Like, in antitrust, you have  
22 to say measurable damages -- I forget what it is -- there  
23 has to be an antitrust violation, there has to be an injury,  
24 and then you have to have measurable damages, or something  
25 like that. In this, it looks as if they've said, if there's

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1 a violation, then you get to damages.

2 MR. MONTGOMERY: I don't see how you have  
3 causation if that's what you conclude.

4 THE COURT: But what if you know it's likely to be  
5 lower, but you just don't know how much lower, where does  
6 that leave me?

7 MR. MONTGOMERY: Well, I think it leaves you in  
8 the land of speculation.

9 THE COURT: Even though you find it's likely to be  
10 a lower FUL, it's just, given the discretionary practices  
11 that are being followed, you can't figure out how much.

12 MR. MONTGOMERY: Well, certainly, your Honor, you  
13 couldn't say that it would likely to be lower in every  
14 single instance. There's no pattern here. You couldn't --  
15 you couldn't from the existence of AMPs conclude what the  
16 FUL would have been in any single instance. You know, if  
17 you were to conclude contrary to what we think is  
18 appropriate that FULs may have been lower on an overall  
19 basis, they may have been lower on an occasional basis, it  
20 doesn't get you to a violation of this statute because  
21 you're only going to get there by talking about what all  
22 defendants might have done. You're really getting into the  
23 land of, you know, enterprise liability, joint and several  
24 liability. We've done no discovery on any relationship  
25 between the defendants. We don't have all the defendants

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1 before you. It's really just not a part of it.

2 THE COURT: Thank you very much.

3 MR. MONTGOMERY: Thank you, your Honor.

4 THE COURT: A quick response, and then I want to  
5 ask the government something.

6 MS. CICALA: Yes, okay. Your Honor, all these  
7 comments about discretion do not go to the issue of  
8 liability at all. They go to the issue of damages entirely.  
9 The violation -- if, for example, defendants had reported  
10 WACs that were actually too low, okay, it's not that their  
11 WACs were overstatements but in fact their true WACs were  
12 higher than what they reported, they still would have  
13 violated 145-b, 1-B. We would still have a violation. It's  
14 a discrete portion of the statute. There is no nexus  
15 between those two provisions, okay? If we have a  
16 Laverdiere/Hillmon situation, right, the fraud just didn't go  
17 right, they still violated the statute. The next question  
18 is, once you have the violation, then you ask how much is  
19 the damage?

20 THE COURT: The reason I keep asking this is  
21 because I have spoken to the mediator in this case, and I  
22 know this is a critical issue for all of you. I mean, I do  
23 know, and I need to resolve it, or it's like a holdup at  
24 this point. I don't know if that's true, but it's my sense  
25 of what it is. Once I rule, and it will take me a while to

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1 do this, it's such a huge record, and it's going to be a  
2 huge amount of time just to rule on it --

3 MS. CICALA: Well, the issue of damages was raised  
4 by defendants. Defendants make the damages argument in  
5 their brief without any support, your Honor, and we address  
6 it --

7 THE COURT: It just seems like any damage figure  
8 is speculative at this point.

9 MS. CICALA: Well, not any, your Honor. We've got  
10 situations where simple rules were applied in the old world,  
11 and simple rules can be applied in the new world.

12 THE COURT: Maybe.

13 MS. CICALA: And we are very comfortable going  
14 down this road and presenting your Honor with a rational,  
15 fair approach to dealing with the damage scenarios here.  
16 And as I said earlier, it may be joint and several, or there  
17 may be mitigating factors that defendants' WACs were ignored  
18 in the old world and would have been ignored again. That  
19 may be a mitigation issue. And that's where all of  
20 Dr. Addanki's comments about discretion come into play.

21 THE COURT: All right, well, thank you. I don't  
22 know. I'm sorry, it's been very, very helpful.

23 Who's here from the Department of Justice? All  
24 right. Oh, you've now moved up to the front bench, okay.  
25 (Laughter.)

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1 THE COURT: So here's my question, and I know  
2 you're a litigant so it's not quite as pure as when I, I  
3 think, asked last time. I think there was a misimpression  
4 from the Department of Justice in the last amicus brief, and  
5 I wanted to know if you wanted to submit another one.

6 MR. FAUCI: If the Court thinks it would be  
7 helpful, I think the Department of Justice would be willing  
8 to do that, your Honor.

9 THE COURT: Well, how about CMS, would you be  
10 doing it on their behalf? Is that it?

11 MR. FAUCI: I'm sure we would, your Honor.

12 THE COURT: The problem I run into is that you've  
13 now got something on the record that's just wrong.

14 MR. FAUCI: And, quite frankly, the amicus brief,  
15 it was written before I was on the case, and it's not  
16 consistent with Ms. Gaston's or Ms. Sexton's testimony. I  
17 think it's probably obvious that the FUL-setting process was  
18 not mechanistic in any way. So if your Honor would think it  
19 would be helpful for an additional briefing, in light of  
20 Ms. Gaston's and Ms. Sexton's testimony, the department  
21 would be happy to do it.

22 THE COURT: Or at the very least, because that's  
23 what's in the record, you need to either revoke the memo or  
24 explain, at least, the government's position, not on the  
25 law, the law of New York -- you don't have any particular

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1 say in that -- but on what happened here, because I, when I  
2 read this the first time through, I have to tell you was  
3 surprised because our working assumption was that it was a  
4 mandatory rule with a mandatory formula; and that just I  
5 think the defendants have very well proven is wrong. I  
6 mean, I think it was worth this exercise.

7 MR. FAUCI: Does your Honor have a time frame on  
8 when this motion would --

9 THE COURT: Not a motion. I don't want a motion.

10 MR. FAUCI: Not a motion, I'm sorry. Piece of  
11 paper.

12 THE COURT: I'm just giving you an option of  
13 revoking that amicus brief, or at least setting forth the  
14 Federal government's position as to what happened during  
15 this period of time; not giving an opinion on New York law,  
16 not giving an opinion on New York law because that's not  
17 special here, and based on this record, not something  
18 different.

19 MR. FAUCI: I think the department would be happy  
20 to do that. The only thing I would just add is, we're  
21 opposing summary judgment motions in the federal intervenor  
22 cases due July 24, and so, frankly, if we could --

23 THE COURT: Pick a date. This is so complex and  
24 so long that it's likely to be a six-month process.

25 MR. FAUCI: I think anytime in mid to late August

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1 we could get you something.

2 THE COURT: Fine.

3 MR. MONTGOMERY: Your Honor just made the point  
4 that whatever they submit, if anything, ought to be based on  
5 this record.

6 THE COURT: This record.

7 MR. MONTGOMERY: I think it is critically  
8 important that if they have any disagreement with  
9 Dr. Addanki's analysis, they need to say so because, as I  
10 have said at some length, the Gaston affidavit is  
11 inconsistent in reality with what they do.

12 THE COURT: I know that's your position. I  
13 just --

14 MR. MONTGOMERY: Well, but it's not been disputed  
15 by plaintiffs, and so --

16 MS. CICALA: Excuse me. I'm sorry, that's not  
17 accurate. What's not disputed by us?

18 MR. MONTGOMERY: You're not disputing Addanki's  
19 analysis.

20 MS. CICALA: No. The exercise of discretion?

21 MR. MONTGOMERY: That's right.

22 MS. CICALA: Well, I'm not willing to -- I do not  
23 embrace the entirety of Dr. Addanki's analysis. We agree as  
24 we have in our papers --

25 MR. MONTGOMERY: There's a record here, your

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1 Honor. There is no dispute.

2 MS. CICALA: As to discretion.

3 THE COURT: I don't know that. I do know this,  
4 which is, I always want to hear from the federal government  
5 interpreting its own regulations and its own policies and  
6 practices. But in fairness, you limited discovery in this  
7 case, not you personally but the government did, you know,  
8 with all the valid Touhy regulations and this, that, and the  
9 other thing, so it can't be stuff that's outside the record.

10 MR. FAUCI: Thank you.

11 MS. CICALA: Your Honor, if I may, with all  
12 respect to Mr. Montgomery, my description of the number of  
13 depositions that occurred as far as I know is accurate.  
14 It's not just two witnesses. Mr. Reed was deposed, who was  
15 Ms. Gaston and Ms. Sexton's supervisor. So I'm not sure  
16 what Mr. Montgomery is referring to when he says there are  
17 only two witnesses.

18 THE COURT: All right, that's fair enough. Just  
19 limited to our record.

20 MS. CICALA: Thank you.

21 THE COURT: It should be limited to our record.  
22 So that would be very useful. Are some of the -- I hate to  
23 say this, but you have a general counsel in place at the  
24 Department of Health and Human Services?

25 MR. FAUCI: There are agency counsel on it.

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1 THE COURT: All right. And there is a head of the  
2 Centers for Medicare and Medicaid Services?

3 MR. FAUCI: The agency counsel, but it is HHS.

4 THE COURT: So we have people -- I understand that  
5 we're in a transition and not all positions have been  
6 filled. You're in a position to take a position for the  
7 federal government?

8 MR. FAUCI: I would assume so.

9 THE COURT: All right. We certainly have an  
10 Attorney General, so that we know.

11 MR. PALERMO: Your Honor, if I may, just one  
12 point. There seems to be an assumption in a lot of the  
13 questioning that dominates today that the defendants have  
14 not reported truthful WACs, and I want the record to be  
15 clear that the defendants, my clients, Dey and the Mylan  
16 defendants, don't concede that at all.

17 THE COURT: I understand.

18 MR. PALERMO: All right, okay. I mean, at all  
19 times they reported truthful WACs consistent with the  
20 federal definition of WAC.

21 THE COURT: You know what, you chose to sit way  
22 back there.

23 MR. PALERMO: I just wanted to make the point for  
24 the record, your Honor, so that it was clear.

25 THE COURT: You've made the record, okay, but at

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1 this point it's been a long day and --  
 2 MR. PALERMO: Thank you, your Honor.  
 3 MS. CICALA: A quick question about the Daubert,  
 4 your Honor.  
 5 THE COURT: Can I tell you, you heard the word  
 6 "Neurontin" come up here?  
 7 MS. CICALA: I know you've had a long day.  
 8 THE COURT: I'm starting trial July 27. I've had  
 9 maybe five or six Daubert motions in that case alone. I  
 10 can't get to this before then.  
 11 MS. CICALA: It's not our motion, your Honor.  
 12 It's defendants' motion. We're opposing it, obviously. I  
 13 just ask whether your Honor would anticipate a hearing on  
 14 that?  
 15 THE COURT: I haven't even, candidly, read it.  
 16 MS. CICALA: Okay, fair enough.  
 17 THE COURT: Okay? So at some point I always have  
 18 a hearing on Daubert motions.  
 19 MS. CICALA: Thank you.  
 20 THE COURT: Whether it's evidentiary or not we can  
 21 talk about, but I always have a hearing on Daubert motions.  
 22 MS. CICALA: Very good. That is our practice too.  
 23 Thank you, your Honor.  
 24 THE COURT: Thank you.  
 25 (Adjourned, 4:35 p.m.)

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1 C E R T I F I C A T E  
 2  
 3  
 4 UNITED STATES DISTRICT COURT )  
 DISTRICT OF MASSACHUSETTS ) ss.  
 CITY OF BOSTON )  
 5  
 6  
 7 I, Lee A. Marzilli, Official Federal Court  
 8 Reporter, do hereby certify that the foregoing transcript,  
 9 Pages 1 through 98 inclusive, was recorded by me  
 10 stenographically at the time and place aforesaid in Civil  
 11 Action No. 01-12257-PBS, In Re: Pharmaceutical Industry  
 12 Average Wholesale Price Litigation, and thereafter by me  
 13 reduced to typewriting and is a true and accurate record of  
 14 the proceedings.  
 15 In witness whereof I have hereunto set my hand  
 16 this 13th day of July, 2009.  
 17  
 18  
 19  
 20  
 21 /s/ Lee A. Marzilli  
 22  
 23  
 24  
 25

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